Program Description Animal Care and Use Program

AAALAC Unit/File Number 000509

United States Environmental Protection Agency

Office of Research and Development

Research Triangle Park Program

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Research Triangle Park, NC 27713

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For AAALAC International

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Program Description

Instructions for Completing and Submitting the Program Description for the Institutional Animal Care and Use Program

Section 1. Introduction

A. State the name of the program unit and, if applicable, its parent organization. List all organizations (schools, centers, etc.) included within the program unit.

The Office of Research and Development (ORD) Research Triangle Park animal care and use Program (RTPP), formerly the National Health and Environmental Effects Research Laboratory animal care and use program, AAALAC Unit 509, is in the Office of Research and Development, United States Environmental Protection Agency (EPA) located in Research Triangle Park (RTP), North Carolina.

The name change is due to the reorganization of the Office of Research and Development and accompanying dissolution of the National Health and Environmental Effects Laboratory (NHEERL) effective October 1, 2019. While the name has changed, the function remains the same.

B. Give a brief overview of the institution, its purpose and how the animal care and use program relates to the mission of the institution.

The Research Triangle Park Animal Care and Use Program of the Office of Research and Development (ORD) of the United States Environmental Protection Agency (EPA) supports research for two ORD Centers: The Center for Public Health and Environmental Assessment (CPHEA) and the Center for Computational Toxicology and Exposure (CCTE). These two Centers encompass comprehensive research programs investigating the effects of environmental pollutants on human health and the environment. These Centers assess, among other things, the risk of environmental chemicals for causing adverse health outcomes and the effectiveness of research for regulatory decision making. In support of these Centers, the RTPP has the capabilities to conduct animal research using oral, dermal, parenteral, and inhalation routes of exposure; to employ a full range of animal toxicology assessment tools including teratology, reproductive toxicology, neurotoxicology and neurobehavioral assessments, pulmonary and cardiovascular toxicology, immunotoxicology, carcinogenicity and genotoxicity. In addition, we have the competence to perform pharmacokinetic studies, physiologically-based pharmacokinetic modeling and predictive toxicity assessment using a variety of computational techniques.

C. Note that AAALAC International's three primary standards are the Guide for the Care and Use of Laboratory Animals (Guide), NRC, 2011; the Guide for the Care and Use of Agricultural Animals in Research and Teaching (Ag Guide), FASS, 2010, and the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe (ETS 123). Other regulations and guidelines used (U.S. Department of Agriculture (USDA), Public Health Service (PHS) Policy, Good Laboratory Practice (GLP), Canadian Council on Animal Care (CCAC), etc.) may also apply. Describe which of the three primary standards and other regulations and guidelines are used as standards for the institutional animal care and use program and how they are applied. For example, an academic institution in the United States with an Office of Laboratory Animal Welfare (OLAW) Assurance may use the standards of the *Guide* and PHS Policy for all animals, the Animal Welfare Act regulations for covered species, and the Aq Guide for agricultural animals used in agricultural research and teaching (see also *Guide*, pp. 32-33). In the European Union, the standards applied might be the *Guide*, ETS 123, Directive 2010/63, and any country-specific regulations.

RTPP maintains an Office of Laboratory Animal Welfare (OLAW) Assurance and uses the standards of the 8th edition of the Guide, PHS Policy, and the US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training for all vertebrate species. RTPP follows the Animal Welfare Act regulations for covered species.

D. Describe the organization and include an accurate, current, and detailed organizational chart or charts (see Appendix 4) detailing the lines of authority from the Institutional Official to the Attending Veterinarian, the Institutional Animal Care and Use Committee/Oversight Body (IACUC/OB), and the personnel providing animal care. Please include the title, name (Note: For individuals whose information is publicly available, provide the titles and names; for individuals whose information is not publicly available, you may provide titles only.), and degree (if applicable) of each individual at the level of supervisor or above. Names of animal care staff below the title of supervisor need not be included, but the titles and number of animal care personnel under each supervisor should be included. If animal care responsibility is administratively decentralized, including the management of satellite housing areas/locations, the organizational chart or charts must include all animal care programs, indicating the relationship between each administrative unit and personnel, the Attending Veterinarian, and the Institutional Official.

RTPP supports the Biomolecular and Computational Toxicology Division (BCTD) and the Chemical Characterization and Exposure Division (CCED) of CCTE and the Public Health and Integrated Toxicology Division (PHITD) in CPHEA. Dr. Wayne

Cascio, Director, CPHEA, serves as the IO for the RTPP. The RTPP receives administrative support from the Facilities and Research Compliance Branch (FRCB) in the Research Support and Compliance Division of the Office of Resource Management. Veterinary and animal care support for the RTTP is provided via contract services. These contracts are administered by the FRCB.

The staffing for CPHEA is 688 people, 276 for CCTE, and 36 for the RSCD. Not all staff members are actively engaged in animal research, nor are they all located in Research Triangle Park, NC.

See APPENDIX 1- Organizational Charts for the following: a) ORD b) RTPP c) Animal Care Staff (contractor); d) Veterinary Care (contractor).

E. Identify the key institutional representatives (including, but not limited to, the Institutional Official; IACUC/OB Chairperson; Attending Veterinarian; animal program manager; individual(s) providing biosafety, chemical hazard, and radiation safety oversight; etc.); and individuals anticipated to participate in the site visit.

Wayne Cascio, MD
Director, CPHEA

Institutional Official (IO) for RTPP and ORD Health IACUC

Michael Narotsky, PhD Health IACUC Chair PHITD

Exemption 6

Director, Animal Resources Program Office RSCD

Leslie Jarrell, JD, DVM, DACLAM Attending Veterinarian (AV) SoBran, Inc.

Exemption 6

IACUC Administrator and Post-Approval Monitor (PAM) RSCD

Exemption 6

Animal Procurement Officer RSCD

Exemption 6

Project Manager, RTP vivarium MPF Federal

Exemption 6, Software Developer

Nonaffiliated IACUC Member

Exemption 6

Manager- Safety, Health and Environmental Management Programs Lieutenant Commander – US Public Health Service CPHEA

F. Briefly describe the major types of research, testing, and teaching programs involving animals and note the approximate number of principal investigators and protocols involving the use of animals. As mentioned in the instructions, please complete Appendix 5 (Animal Usage) or provide the information requested in a similar format as an Appendix.

All RTPP research protocols focus on the toxicity of environmental contaminants. Recently the chemical species of study have included gaseous and particulate air pollutants including combustion products for wildfire research, volatile organic compounds, water disinfection byproducts, nanomaterials, air particulates, flame retardant compounds, insecticides, herbicides, fungicides, metals, and algal toxins.

Currently the institution has 23 principal investigators. Approximately 20 research protocols (referred to as Animal Care and Use Protocols or ACUPs) involving the use of animals are approved by the IACUC annually, with an additional 60 amendments reviewed and approved. As of November 14, 2019, there have been 38 active animal protocols in the ACUP system (RTPP electronic animal protocol database). (See Appendix 5).

The research staff has the capability to evaluate the impact of environmental toxicants on reproduction including performance, behavior and hormones; immune response; behavior, neurophysiology, neurochemistry and homeostasis; pulmonary and cardiovascular responses; pharmacokinetics and mechanisms; genetic damage and gene expression.

RTPP also maintains one teaching protocol, used by the Animal Resources Program Office (ARPO) to train and ensure competency of animal handlers. The single teaching protocol covers the rodents used at the institution, basic handling, and some specialized techniques such as aseptic surgery. Additionally, one sentinel animal protocol and one animal holding protocol are maintained by the ARPO.

G. Note the source(s) of research funding (grants, contracts, etc.) involving the use of animals.

As a part of the US Environmental Protection Agency, the Centers and RTPP currently receive all operating funds from the U.S. Federal Government via Congressional appropriations. RTPP maintains a PHS Assurance (A4051-01) in order to allow researchers to collaborate with colleagues receiving federal funds. Some students have applied for NIH fellowships through their institutions of higher learning. When these fellowships are successful, the university handles administration of the fellowship and any accompanying funds and EPA does not receive any financial support.

H. List other units (divisions, institutes, areas, departments, colleges, etc.) of your organization that house and/or use animals that are not included in this Description. If any of these are contiguous, physically or operationally (e.g., same IACUC/OB, same animal care staff), with the applicant unit, describe the association. Explain why such units are not part of this program application.

Note: Questions regarding this section should be forwarded to the AAALAC Office.

RTPP does not currently have any other units which house and use animals which are not covered by this program description. ORD has 4 other sites around the country which do house and use animals. None are physically contiguous; some portions of operation are now shared. There is an AAALAC Accredited EPA/ORD facility in Cincinnati, OH. There are also aquatic facilities performing research with vertebrates in Duluth, MN; Narragansett, RI; and Gulf Breeze, FL. ORD has begun the process to harmonize animal care and use across all these sites. Administrative resources including IACUC functions and some veterinary consultation services are shared with these distant sites. The IACUCs are distinct, though the Health IACUC (RTP, NC) and the Ecology IACUC (MN, FL, RI) share some IACUC members, the IACUC Administrator, and the IO. The goals of the programs are also all distinct. These programs will not be rolled into one Accreditation with the RTPP.

I. Contract Facilities: If the institution contracts for animal care facilities or services for animals owned by the institution, the contractor and its AAALAC International accreditation status must be identified. If a contractor's animal care and use program is not accredited by AAALAC International, a brief description, following this Program Description outline, of the relevant contractor's programs and facilities must be provided. In addition, the species and approximate average number of animals housed in the contract facilities and the approximate distance between the institution's animal facility and the contract facility must be noted. Incorporation of the contractor program into the site visit schedule will be discussed with institutional representatives. If the institution does not contract for animal care facilities or services, so note.

RTPP does not currently have any contracts for animal care facilities or services with any other entities. RTPP does receive contract support to maintain the RTP animal facilities; this support is evaluated as part of this program.

J. Note other relevant background that will assist reviewers of this report.

The RTPP has undergone a lot of changes in the last 3 years, many significant ones in the last few months.

The Office of Research and Development reorganized in 2019, dissolving the 7 National Centers and National Laboratories, including the National Health and Environmental Effects Research Laboratory which had previously been the sole functional unit and support for this program, restructuring into 4 Centers. Administration is being centralized to optimize efficiencies and share resources; this is very much still a work in progress. The staff members directly in support of the RTPP have been pulled out of the research level of the organization into the administrative level, allowing support of multiple facilities and IACUC programs across the country. This reorganization results in the RTPP now supporting CPHEA and CCTE, while the Animal Resources Program Office supports 2 additional IACUCs and assists with support of 4 additional animal facilities. The details are still a work in progress.

There have been other significant changes and challenges since the last program review.

The longtime Director of the Animal Resources Program Office (ARPO) in RTP, **Exemption 6**, retired in 2017, and a new Director, **Exemption 6**, was hired from within. This resulted in a cascade of changes culminating in the hires of a new IACUC Administrator, **Exemption 6**, and a new Animal Ordering Officer, exemption 6, over the course of 2018. The Director of the National Health and Environmental Effects Research Laboratory, **Exemption 6**, appointed a new IO, Kay Holt, in 2018, and retired himself later that year. The new IO served until March 2019, when the new NHEERL Laboratory Director, Wayne Cascio, stepped in as IO. Dr. Cascio has agreed to serve as IO for both the Health IACUC, the IACUC serving the RTPP, and the integrated Ecology IACUC which serves 3 facilities around the country.

There have been significant changes in the operations and maintenance of the RTP vivarium. In late spring and early summer of 2018 two key personnel on the contract providing animal care and husbandry left, including the Project Manager for the facility. This Project Manager had worked in the facility on one contract or another for well over 30 years, and the loss was significant. Following performance issues, the animal care contract itself turned over and a new contract with a new Project Manager, **Exemption 6**, was awarded late May 2019. By November of 2019 all key personnel from the prior contract have turned over; one key position is still unfilled.

Additionally, the electronic software system used by the RTP animal care and use program for protocol review (scientific merit and IACUC review both) and animal purchases was retired. In-house development of new software began in 2016,

accelerated in 2017, and new software was rolled out to research and administrative staff late 2018, with revisions and development continuing through the present. This electronic system, ACUP/AR (for Animal Care and Use Protocol/Animal Requests), will be extended to the other animal care and use programs in ORD over the next few years.

ORD continues to operate under a tightened Federal Budget and therefore hiring is limited. Following the reorganization, new positions have opened which may increase the number of animal users in the future and may influence the type of animal work performed by this program, but hiring is expected to be slow for the foreseeable future.

Finally, EPA in general and the RTP program specifically has participated in two government wide General Accounting Office inquiries and a few direct Congressional Inquiries regarding animal research in the Federal Government. While there were no findings for EPA in these inquiries, the interest in the EPA animal programs contributed significantly to the restructuring and harmonizing of ORD's animal programs across the country.

b

Section 2. Description

I. Animal Care and Use Program

A. Program Management

1. Program Management Responsibility [Guide, pp. 13-15]

a. The Institutional Official [Guide pp. 13-14]

Describe how program needs are clearly and regularly communicated to the Institutional Official by the Attending Veterinarian, IACUC/OB, and others associated with the program.

The Director of the Animal Resources Program Office, the IACUC Chair, the AV, and the IACUC Administrator hold regular monthly meetings with the IO.

The IACUC submits semiannual reports to the IO.

b. Role of the Attending Veterinarian [*Guide*, p. 14]

- i. Describe the institutional arrangement for providing adequate veterinary care. Although individual name(s) and qualifications will be described below, identify by title the veterinarian(s) responsible for the veterinary care program, including:
 - a list of responsibilities
 - a description of the veterinarian's involvement in monitoring the care and use of laboratory animals
 - the percentage of time devoted to supporting the animal care and use program of the institution if full-time; or the frequency and duration of visits if employed part-time or as a consultant.

Note: If preferred, this information may be provided in a Table or additional Appendix.

The current institutional arrangement for providing adequate veterinary care is through a legal contract with SoBran, Inc, which provides the full time services of Leslie Jarrell, JD, DVM, Diplomate ACLAM, as Attending Veterinarian (AV).

Dr. Jarrell devotes 100% of her time to the care of ORD's animals. Veterinary services include but are not limited to:

- hands on care and treatment of individual animals
- providing guidance for research and animal care staff
- serving as a full voting member of the ORD Health IACUC serving RTP

- reviewing protocols, operating procedures and techniques
- performing animal health checks
- offering consultation on all aspects of animal welfare including but not limited to biosecurity, social housing, enrichment, pain or distress, anesthesia and analgesia, diet, handling and restraint, euthanasia, emergency preparedness, environmental conditions (light, water quality, temperature etc.)
- teaching hands-on training classes for animal handling, basic procedures, aseptic technique and basic surgical techniques development and planning of animal experiments by providing assistance with choice of appropriate models, techniques, anesthetics and analgesics, and adequate post-experimental and post-operative monitoring
- advising the ARPO Director on the oversight of the animal care and husbandry program including issues of compliance with federal, state, and institutional regulations and policies.

When Dr. Jarrell is not available, veterinary services are provided by **Exemption 6**, DVM, DACLAM, or other back up veterinarians.

Veterinary coverage is also provided on-call evenings, weekends and holidays.

ii. List others (e.g., Principal Investigators, veterinarians serving as Principal Investigators, veterinary faculty/staff, technical staff, farm managers) who have a direct role in the provision of veterinary care and describe their responsibilities. The Organizational Chart(s) provided in Appendix 4 must depict the reporting relationship between these individuals and the Attending Veterinarian.

Note: If preferred, this information may be provided in a Table or additional Appendix.

Exemption 6: Animal Health Technician (AHT)

Responsibilities include:

- perform animal exams to detect abnormalities,
- provide clinical treatments (e.g., injections, sample collections) as directed by AV,
- perform necessary anesthesia and euthanasia for all species,
- maintain and update Animal Health Reports (AHRs), sending notices to research staff regarding proposed treatment or euthanasia,
- perform minor surgical procedures using aseptic technique,

- assist with training animal care and research staff on proper animal handling and various veterinary procedures (where appropriate),
- fully support AV in daily activities.

Animal Care Staff (ACS) responsibilities:

- Early detection and recognition of animal pain and distress,
- Early detection and recognition of possible animal disease states,
- Prompt notification of any possible animal health problems via Animal Health Report (AHR)
- Veterinary tasks as assigned by AV and/or AHCT,
- Closely monitor and treat animals with active AHRs,
- Animal euthanasia.

Research staff working with animals do not hold primary responsibility for veterinary care but are expected to monitor animal health and wellbeing and intervene as appropriate. Research staff generally ask for the assistance of the AV when health issues arise.

c. Interinstitutional Collaborations [Guide, p. 15]

Describe processes for assigning animal care and use responsibility, animal ownership and IACUC/OB oversight responsibilities at off-site locations for interinstitutional collaborations.

RTPP collaborates with PHS assured and AAALAC accredited institutions via contractual agreements, memorandums of understanding, and occasional grants. Animal care and use responsibility, animal ownership, and IACUC oversight have been the purview of the institution where the animals are housed and the work performed, though the HEALTH IACUC requires copies of the IACUC approved Animal Care and Use Protocols from these other institutions. There is currently nothing formalized following the reorganization of ORD.

2. Personnel Management

a. Training, Education, and Continuing Educational Opportunities

Describe how the IACUC/OB provides oversight and evaluates the effectiveness of training programs and the assessment of personnel competencies. Describe how training is documented.

Note: Do not include details about the training program, which should be described in the following sections.

The ARPO and IACUC oversee the training of all new animal handlers on the research staff by requiring online training (AALAS Learning Library modules) and hands-on training for mammalian species before any individual is allowed to work with animals or be granted key card access to the animal holding rooms.

Evaluation of the training program is accomplished by periodic review of training program materials, feedback from trainees, and observed technique during IACUC Semi-annual Facility Inspections, Post Approval Monitoring visits, and observation by the AV, ACS or other staff while individuals work with animals. The IACUC receives Training Reports from the AV and IACUC Administrator during quarterly business meetings. The IACUC is also updated by the AV regarding any special researcher requests for training or special training sessions as they occur.

AALAS Learning Library transcripts, records of attendance at in-person training sessions, and Certificates of Training are maintained on file in the ARPO. A spreadsheet which covers training and dates of completion is also maintained by the IACUC Administrator for quick reference.

The same process is used for any necessary additional or re-training of staff.

Records of initial training and continuing education for the Animal Care Staff are maintained by the Facility Manager and reported to the IACUC at June & December quarterly business meetings.

i. Veterinary and Other Professional Staff [Guide, pp. 15-16]

For the Attending Veterinarian and other individuals having a direct role in providing veterinary medical care (veterinarians, other professional staff listed above, private practitioners, etc.), provide: name, credentials (including degrees), and a description of their qualifications, training, and continuing education opportunities.

Note: Please do not provide curriculum vitae of personnel; if preferred, this information may be presented in a Table or additional Appendix.

Leslie Jarrell, JD, DVM, DACLAM

Attending Veterinarian, contracted with SoBran, Inc

Qualifications: Dr. Jarrell was accepted by the American College of Laboratory Animal Medicine (ACLAM) as a diplomate in 2012.

Training: Dr. Jarrell received her Juris Doctor degree (J.D.) from University of California- Davis, School of Law, Davis, CA in 1993. She received her Doctor of Veterinary Medicine degree (D.V.M.) from the University of California- Davis, School of Veterinary Medicine, Davis, CA in

1997 and completed a 3-year Laboratory Animal Medicine Residency program at University of North Carolina, Chapel Hill, NC in 2009.

Continuing Education: Dr. Jarrell completes at least 20 hours per year of veterinary continuing education through both laboratory animal medicine meetings and other veterinary meetings. She attended and lectured at the 2019 NC Workshop in Laboratory Animal Medicine. She attended the 2019 NCABR IACUC conference, the 2018 North Carolina Veterinary Conference, and local North Carolina Academy of Laboratory Animal Medicine meetings. Dr. Jarrell provides didactic lectures for the Research Triangle Park Laboratory Animal Medicine Training Program as well as lectures at local grade schools.

Francis J. Sun, DVM, DACLAM

Veterinarian, contracted with SoBran, Inc.

Qualifications: Dr. Sun was accepted by the American College of Laboratory Animal Medicine as a diplomate in 2004. Dr. Sun has also been an ad hoc consultant for AAALAC since 2010.

Training: Dr. Sun received his Doctor of Veterinary Medicine degree from the North Carolina State University, College of Veterinary Medicine in 1996.

Continuing Education: Dr. Sun completes at least 20 hours per year of veterinary continuing education through both laboratory animal medicine meetings and other veterinary meetings. Dr. Sun lectures at various lab animal conferences and for the Research Triangle Park Laboratory Animal Medicine Training Program.

Exemption 6, AAS

Animal Health Technician

Qualifications: received her AAS in Animal Health Science from Camden Community College, Blackwood, New Jersey in 1986. She received the Assistant Laboratory Animal Technician Certification in June 1992 and the Laboratory Animal Technician certification in October 1993.

Continuing Education: Exemption 6 attends continuing education opportunities hosted by RTB AALAS and National AALAS webinars.

ii. Animal Care Personnel [Guide, p. 16]

1) Indicate the number of animal care personnel.

There are currently 19 members on the Animal Care Staff (ACS).

2) Summarize their training, certification level and type, experience, and continuing education opportunities provided.

Note: If preferred, this information may be provided in a Table or additional Appendix.

All personnel detailed below have received in-house training by the managers and supervisors on: 1) proper animal husbandry, 2) humane care and use of lab animals, 3) basic lab animal biology, 4) animal euthanasia and, 5) safety. Training materials and opportunities include RTP Animal Facility SOPs, AALAS manuals, instructional videos, workshops, and seminars. Training is an ongoing process.

Competency Observance:

Individual staff are observed and judged (unannounced) on their competency and observance of facility SOPs by the project manager, animal health care technician, or operations manager. Where deficiencies are noted corrective action is immediately taken and follow-up observation scheduled.

Refresher training is presented whenever a technical assistance request is made for procedures not being routinely performed, e.g., animal dosing and injections, BSL II animal husbandry techniques, breeding colony support.

Ongoing Training:

Staff are encouraged to attend and/or participate in any on-site training conducted by EPA SHEM or the AV. A number of contractor staff routinely assist the AV in training exercises

Staff are encouraged to attend ARPO hosted webinar which present subject matter germane to their duties.

All animal care personnel are also encouraged to become members of the local AALAS branch (Research Triangle Branch), thus being able to take advantage of continuing education through monthly programs, workshops, seminars and district meetings.

Once eligible, all animal care personnel are strongly encouraged to become AALAS certified. Currently AALAS certification = 47% of animal handlers on staff. Additional staff members plan to test for certification soon.

Staff:

Manager: 1

Experience: 28 years

LATg certified, Registered Veterinary Technician (Maryland)

Supervisors: 2

Average experience: 33 years

1 ALAT certified

QC Lab Technicians: 3

Average experience: 26 years

1 ALAT certified1 LAT certified

Animal Health Specialist: 1 AAS in Animal Science

LAT certified

Experience: 12 years

Lab Animal Technicians: 8 Average experience: 20 years

3 ALAT certified

Administrative Assistant: 1 Experience: 20 years

ALAT certified

Equipment Preparation Aides: 3 Average experience: 20 years

Aquatics Specialist: 1

Pending new hire as of 10/25/2019

iii. The Research Team [Guide, pp. 16-17; 115-116; 122; 124]

- 1) Describe the *general mechanisms* by which the institution or IACUC/OB ensures that research personnel have the necessary knowledge and expertise in the animal procedures proposed and the species used.
 - 1. The Animal Care and Use (ACUP) form contains a table which asks for a listing of personnel, their duties, and their relevant training. The IACUC reviews this table during all protocol reviews. All required training must be completed prior to IACUC approval of the ACUP (or amendment) and before animal holding room access is granted.
 - 2. All new animal handlers must complete a form (Experience Research Animal Survey) that details their previous experience with specific animal related procedures. The form is stored electronically on the ORD Animal Resources network drive and may be reviewed by the AV, IACUC, and PAM.

- 3. New animal handlers are required to take and pass the exams for a core series of basic training modules in the AALAS Learning Library, including occupational health, ethics, research mandates and IACUC function, and species-specific basics. Additional modules appropriate to their work (anesthesia and analgesia, aseptic technique) must be completed before individuals are allowed to perform those procedures.
- 4. All new employees, contractors or students who will be handling mammals must take and successfully complete a species-specific hands-on animal handling lab under the instruction of the AV before handling live animals. (Rat 101, Mouse 101, Rabbit 101)
- 5. If an ACUP indicates that an individual will be taking part in procedures for which they do not have the necessary experience and expertise not already addressed by programmatic training, the IACUC requires the investigator to detail in the ACUP how training will be provided and by whom.
- 6. The Building A vivarium has strict biosecurity requirements. All individuals working in the Building A vivarium must complete biosecurity barrier training, including a guided tour of the facility, with an Animal Barrier Committee (ABC) member, before access to the facility is granted.
- 7. Competence in animal handling, animal procedures and barrier technique is considered during PAM visits and IACUC Semiannual Facility Inspection, with additional input provided by veterinary and animal care staff observations.

A listing of all required and recommended training is available on the ORD IACUC intranet website and is provided to all incoming personnel as part of a welcome letter.

a) Briefly describe the content of any required training.

All new animal users are informed about the ORD methods of reporting concerns about animal care or use in the letter sent to all new animal users outlining the required training. The methods of reporting concerns are also posted in the airlocks to the animal facility, on the IACUC website, and again discussed during hands-on training sessions.

Topics covered by the on-line AALAS Learning Library training include: animal care and use legislation, IACUC function, ethics of animal use, the 3 R's, occupational health and safety issues pertaining to animal use, species specific information (including but not limited to basic handling, husbandry and euthanasia). Other

subjects, such as aseptic surgical technique, anesthesia and analgesia and breeding colony strategies, are addressed on an as needed basis via the Learning Library or alternative sources (i.e., Jackson Laboratory tutorial).

The rodent hands-on training contains a didactic portion which covers the following topics: introductions to the RTP Training Colony, and Personal Protective Equipment (PPE), basic restraint and handling, options for restraint for procedures, methods of identification, recognition of pain and distress, analgesia, euthanasia, emergency contact information, health reports and animal bites. Trainees are then introduced to live animal handling. Socialized rats are the first rats handled by new animal users. These socialized animals build confidence in new handlers as the students learn basic skills such as how to appropriately lift or restrain an animal. Students are then moved on to less socialized animals where they again practice basic handling and restraint. All students are taught euthanasia by CO₂ asphyxiation followed by a secondary physical technique. Proficiency must be demonstrated before a student can successfully complete Rat or Mouse 101. Some classes may additionally cover procedures based on student need and interest, including: injections, blood collection techniques and basic necropsy. The mouse training class follows a similar pattern, but no mice have been socialized.

New surgical personnel are required to take aseptic technique dry and wet labs (3+ hours each). The drylab emphasizes pre-surgical planning, records and supplies, anesthesia, analgesia, surgery area, heat sources, aseptic technique, donning gloves, the sterile field, what steps to take if sterility is broken, rodent serial surgeries, glass bead sterilizer use, suture types, recognition of pain and distress, health reports and emergencies, post-operative care and post-operative complications, and suture removal. The wetlab puts the items learned in the drylab into practice, and expands on presurgical planning, gentle tissue handling and surgical technique with a focus on suturing technique and practice.

RTP maintains biosecurity of the A wing animal facility using a barrier system. All individuals with need to work inside the barrier must be trained by a member of the Animal Barrier Committee (ABC) before key card access to the facility will be granted through the Animal Resources Program Office. ABC members are representatives from each floor of the facility, and generally train newcomers working on their floors. Training involves becoming familiar with the A building operating procedure, understanding how to appropriately dress in and out of the facility, understanding traffic

patterns within the facility, and a personalized tour of the A wing facility with a member of the ABC.

The Safety, Health and Environmental Management (SHEM) program also maintains an extensive safety training program at the institutional level, above the IACUC or animal care and use program. This program includes Initial Safety, Health and Environmental Management Training (ISHEM) which is required for all new laboratory workers, annual SHEM Core training, as well as Radiation Safety training, Waste Management training, fire extinguisher training and other sessions based on an individual's identified risks or needs.

b) Describe the timing of training requirements relative to the commencement of work.

All online training must be completed before a person, regardless of background, may work with animals, and the training will be verified when the individual is added to required animal use protocol(s). All hands-on rodent handling training must be completed before new hires, regardless of background, are allowed to work with live rodents. Hands-on training will be verified when the individual is added to required animal use protocol(s). Specific training provided by the investigative staff must be described in a protocol or amendment which will be reviewed by the IACUC, and the IACUC requires a person be identified by the lab to oversee the trainee until competence is assured.

Individuals may also receive hands-on training or retraining if there is need.

All Barrier Training must be completed before a person may enter the animal facility unescorted. Barrier training is provided by members of the Animal Barrier Committee to individuals on an as needed basis.

Initial Safety, Health and Environmental Management (ISHEM) training allows for new staff to work in the lab in only very limited circumstances before completing their ISHEM training: they may work in the lab in the physical presence of the PI or other qualified laboratory personnel and then only if there are no chemical or physical hazards involved and no exposure potential present (such as from other people working in the lab). Practically, ISHEM needs to be completed before a new hire may work in a laboratory.

c) Describe continuing education opportunities offered.

The AALAS Learning Library, inclusive of the modules for Certification, is available upon request to any interested ORD employee.

Specific hands-on technique classes are available on request, as IACUC recommended refresher training, or on an as needed basis. These classes have included training in anesthesia, aseptic technique dry and wet labs, facial vein or tail vein blood collection, and oral gavage. New training has been created when the need presented.

Webinars, such as those offered by AALAS, are available to interested parties. Online training, such as the Jackson Laboratories training, is available. Investigative staff are also invited to attend the live OLAW, AALAS, AAALAC, and PRIM&R webinars when these are offered by the ARPO, as applicable to their work and interests.

Some research laboratories also send their staff to species or technique specific workshops, such as aquaculture or surgical technique training. This last type of training is encouraged by the animal program but not required.

- 2) Describe the process(es) to ensure surgical and related procedures are performed by qualified and trained personnel, including:
 - who determines that personnel are qualified and trained for surgical procedures
 - the roles that the Attending Veterinarian and IACUC/OB have in this determination [Guide, pp. 115-116]

New surgical personnel are required to take the hands-on basic surgical procedures and aseptic technique dry and wet lab 4 class series taught by the AV, with assistance from training staff, as discussed above. Proficiency of these surgeons is evaluated by the training staff during that lab.

Additionally, the IACUC requires a listing of all personnel, what tasks they will be performing, and what appropriate training they have completed in both the ACUP and Amendment forms. The IACUC, including the AV, reviews this section to ensure all staff is adequately trained. The IACUC Administrator may be required to provide transcripts to document training. Instruction in project specific procedures may be provided by the investigative staff; the IACUC requires that the PI or designee provide oversight until competency is achieved.

Finally, both the AV and PAM make a point of visiting surgical labs to observe procedures performed and assess skill.

3) Describe the training and experience required to perform anesthesia. [*Guide*, p. 122]

Anesthesia is treated as a separate but related subject to surgery. Staff members are required to complete an anesthesia wet lab class. Skill is also assessed during basic surgical procedures and aseptic techniques dry and wet lab series, and laboratory visits from the AV or PAM.

4) Describe how the proficiency of personnel conducting euthanasia is ensured (especially physical methods of euthanasia). [*Guide*, p. 124]

For the research staff, basic methods of euthanasia are covered by both the AALAS Learning Library species specific modules and the hands-on training provided by the ARPO. The trainee is not certified as proficient until the trainer is satisfied that the procedure has been accomplished properly during Mouse 101 or Rat 101 classes. Subsequent instruction in euthanasia methods is received directly from experienced primary investigators/scientific staff or the Attending Veterinarian. Proficiency is also observed during PAM visits. Additional observations are provided by the veterinary staff and the animal care staff. Refresher classes are provided as needed. For protocols with one team member responsible for specific euthanasia methods, the IACUC ensures that a more readily accessible method is available for days that the team member is not present (ie. PI uses cervical dislocation, but other team members are not proficient in this method as sole method, so they instead may use CO₂ asphyxiation.)

ACS members receive hands-on instruction from the management and supervisory staff in proper euthanasia techniques. No ACS member may perform euthanasia until they have satisfactorily demonstrated their proficiency in the presence of an instructor. In addition, proper euthanasia practice is reviewed in training sessions.

b. Occupational Health and Safety of Personnel [*Guide*, pp. 17-23]

- i. Institutional Oversight [Guide, pp. 17-19]
 - 1) List the institutional entities (units, departments, personnel, *etc.*) that are involved in the planning, oversight, and operation of the institutional occupational health and safety program related to animal care and use (e.g., office(s) of environmental health, institutional health services or clinics (*including contracted health services*), industrial hygienists,

Institutional Biosafety Committee(s) and/or Officer(s), Radiation Safety Committee(s) and/or Officer(s).

- Include a brief description of their responsibilities and qualifications.
- If contracted services are used, also include their location (e.g.,remote offices to which personnel must report).

The Office of Resource Managment (ORM), Research Support & Compliance Division (RSCD) provides direct support to the ORD Health IACUC through their two Branches and Immediate Office (IO).

- 1) Safety, Health and Environmental Management Branch (SHEMB): SHEMB has the primary responsibility for laboratory related safety, health, and environmental management at RTP. SHEMB employs four federal employees, three support contractors, and one administrative Senior Environmental Employment (SEEP) program employee. Areas of expertise include: occupational safety, health and compliance; industrial hygiene; environmental compliance; hazardous materials shipping; emergency planning and response; radiation and laser safety; biosafety; and other safety and health-related fields. SHEMB is regularly consulted in matters of safety, health, and environmental compliance. The SHEM Industrial Hygienist serves as the backup health and safety ORD Health IACUC Committee member and coordinates.
- 2) Facilities & Research Compliance Branch (FRSCB): The FRSCB is responsible for facility managment, protection of government assets, and regulatory compliance. The FRSCB administers the ORD Health IACUC to ensure regulatory compliance and accreditation and has multiple ORD Health IACUC Committee members within the Branch. environment for animals and workers. They respond to emergencies, repair facility defects and system malfunctions, and direct new construction and renovation projects. They employ a formally-trained safety and health manager and contractor who possesses a certification in industrial hygiene who, among other duties, responds to indoor air quality issues and other safety and health issues that are facility-related.
- 3) Immediate Office (IO): The IO employs one federal Industrial Hygiene and Safety Manager. This person functions as the IACUC occupational health representative, has a formal background in industrial hygiene and occupational safety and health, and is a Registered Environmental Health Sanitarian (REHS). The priority function of this member is to identify and address employee health and

safety hazards anticipated from the protocol and manage any additional environmental management impacts.

Other Safety-Related Participants:

RTP-Office of Mission Support - Facilities Support Branch (FSB): FSB employs various federal and contract employees that have diverse safety, health and environmental backgrounds. FSB provides facilities management support for the entire RTP campus and administers various facility-related policies and procedures. FSB maintains responsibility for facility emergencies, security, facility and system repairs and malfunctions, and direct new construction and renovation projects.

Animal Care Contractor: The animal care contractor has, by contract, health and safety programs in place for their own company functions. However, as a multiemployer worksite, the federal safety and health staff has responsibility for overall health, safety, and environmental program management on site since EPA can be the controlling, exposing, correcting, and creating employer in terms of hazard situations.

Attending Veterinarian Contractor: The Attending Veterinarian contractor has, by contract, health and safety programs in place for their own company functions. However, as a multiemployer worksite, the federal safety and health staff has responsibility for overall health, safety, and environmental program management on site since EPA can be the controlling, exposing, correcting, and creating employer in terms of hazard situations.

2) Describe methods to identify work-related hazards and the processes used to evaluate the significance of those hazards in the context of duties and tasks. Describe both common approaches and differences, if applicable, for categories of personnel such as, but not limited to, researchers, veterinarians, husbandry staff, cage-washing staff, students, housekeeping, physical plant staff, security personnel, IACUC/OB members (including non-affiliated members), contractors, visitors, etc. [Guide, pp. 18-19; see also Chapters 2 and 3 in Occupational Health and Safety in the Care and Use of Research Animals, NRC 1997.].

Hazard identification and risk assessment: Systems are in place that contribute to the identification and assessment of risk regarding laboratory safety and ensure the appropriate monitoring activities take place. Systems in place include: 1) Job Hazard Assessments (JHAs); 2) Health and Safety Research Protocols (HSRPs); 3) Laboratory

Animal Protocol Reviews (ACUP), and; 4) chemical procurement safety and health reviews.

- 1) (JHAs): Review of activities take place at all EPA facilities in order to determine hazards or potential hazards with the goal of reducing or eliminating workplace exposure. EPA requires that each workspace is inspected annually for hazardous conditions. Comprehensive assessments include review of hazardous and exposure characteristics of chemicals and other disease agents, real-time and integrated air sampling to determine personal exposures, air flow measurements, literature review, and other assessment activities, as required.
- <u>2) HSRPs</u>: Any employee using a substance that is deemed highly hazardous must submit a HSRP that is reviewed by a committee of industrial hygienists, environmental compliance officers, and other safety personnel prior to granting employees approval to use the hazardous substance. Information required on HSRPs include: 1) description of the study highlighting hazardous processes; 2) authorized personnel and their training and experience; 3) a list of chemicals and other dangerous agents; 4) location(s) of work and processes; 5) waste disposal methods, and; 6) emergency response.
- 3) ACUP: The ACUP review process includes a section that identifies chemicals administered to animals and is reviewed by the ORM-IO Industrial Hygiene and Safety Manager who is a permanent member on the IACUC. The Principal Investigator (PI) requesting ACUP approval is required to list all substances administered to animals as well as the respective toxicological values (i.e. LD50, LC50). If the substances are deemed hazardous, the related HSRP must be listed. Oftentimes, a HSRP has not been developed and through the ACUP process the hazards are identified. The PI is contacted and asked to submit a HSRP request, thus activating the HSRP review process.
- 4) Chemical Procurements: Safety Review and Approval: All chemicals ordered by investigators must be approved by the SHEM Branch. The procurement system is set up such that all chemical orders are automatically routed to the safety and health reviewer who reviews the order to ensure that any hazardous chemicals are included on a HSRP. If proper documentation and controls are not in place for highly hazardous substances, the safety and health reviewer withholds approval until the documentation and controls are in place.

Control and prevention strategies:

Exposure control is a multi-tiered, prioritized approach. In order of priority, the control strategies are as follows: Substitution/Elimination;

Engineering; Administrative; Work Practices; and Personal Protective Equipment (PPE).

Substitution/Elimination takes place before any animal research will have been proposed and will not be addressed here.

Engineering: Facilities, equipment, and monitoring: Primary engineering exposure control is general ventilation and the use of chemical fume hoods and biological safety cabinets. The design of the facility is such that hazards are confined to areas of use and any need for transporting hazardous substances is reviewed by SHEM staff who will dictate any processes to ensure optimal safety and health conditions. Monitoring of hazardous substances occur when appropriate and may include realtime air sampling, integrated sampling, or static monitoring over the course of the hazardous process. Further, fume hoods are certified initially using the American Society of Heating, Refrigeration, and Airconditioning Engineers (ASHRAE) 110 Standard Method: "Method of Testing Performance of Laboratory Fume Hoods." The hoods are then certified annually according to Procedures for Certifying Laboratory Fume Hoods to Meet EPA Standards by an outside contractor specializing in chemical fume hoods to ensure proper operation and containment capability. Biological safety cabinets are certified upon installment and annually thereafter according to the National Sanitation Foundation (NSF) 49 Standard Method: "Biosafety Cabinetry Certification", which is the international standard for BSC design and testing criteria.

Administrative: ACUP and CAT:

ACUP: The RSCD immediate office health and safety representative is a permanent member of the ORD Health IACUC and reviews all protocols. Once the ACUP process identifies particularly hazardous agents being used, the PI is contacted and advised to submit an HSRP if one is not already in place. Hazards will then be assessed, and necessary controls will be implemented as part of the HSRP process.

Chemical Alert Tags (CATs): An animal program specific procedure is in place to alert Animal Care Staff and other contract employees in the animal facility of potential hazards created by research processes that involve dosing animals with a highly hazardous substance. This system uses a CAT to inform employees of existing chemical hazards, ensure emergency contact information is available, and notify employees of necessary PPE requirements. CAT tags are developed and implemented with consultation between the SHEM, researcher, animal care staff, and animal care and use program staff.

Work Practices: Personnel Training and Personal Hygiene

Personnel Training: Safety and health training for federal employees begins at the onset of laboratory employee's arrival at our facility and is required of all employees working in laboratories. The initial course is eight hours in length and encompasses all written safety and health policies and procedures as well as environmental compliance. Such topics as animal allergies, zoonoses, reporting of injuries, chemical hygiene and so on are covered. An annual safety and health refresher course, which is a requirement for all laboratory employees, provides annual refresher training in specific OSHA, EPA, Department of Transportation (DOT), or Nuclear Regulatory Commission (NRC) regulations.

Safety and health training for contracted animal care staff and the Veterinarians is primarily the responsibility of their contractor management. These personnel receive initial training and annual refreshers regarding hazards commonly found in animal care environments. ORD SHEM training (ISHEM and SHEM refresher) is available to animal care personnel and those animal care personnel who work in laboratories are especially encouraged to attend.

Personal Hygiene: Personal hygiene requirements are written into the EPA-RTP Chemical Hygiene Plan. Among these requirements are policies that address appropriate behavior, eating, smoking, applying cosmetics, and so on. A most important hygiene practice is hand washing. Employees are directed to wash their hands before donning and after doffing personal protective equipment, and before exiting the laboratory environment.

Personal Protective Equipment (PPE): PPE is provided to all staff with descriptions of PPE being detailed later in this document. Animal Facility PPE provided at the entrance to the animal facility includes disposable lab coats and disposable shoe covers. Surgical masks and nitrile gloves must be donned when entering an animal holding room. Laboratory PPE is laboratory specific based on the hazards in use in the lab.

3) Describe methods and frequency of reassessing work-related hazards.

Semi-annual SHEM Safety Audits

Comprehensive semiannual safety audits are conducted by the SHEM Branch. This includes a "floor-to-ceiling" inspection of all laboratory,

office, and animal areas. Findings are released to all employees and action is required to mitigate each finding.

Reoccurring Industrial Hygiene Exposure Monitoring

Employee exposure monitoring is conducted for a variety of substances and an established re-sampling frequency is determined based on exposure results. In most cases, substances (i.e., isoflurane, formaldehyde) are re-sampled every two years due to well-controlled conditions (i.e., used in fume hood/BSC) and low concentrations. Industrial hygiene resampling frequency criteria is based on industry guidance provided by multiple scientific organizations (ACGIH, AIHA, NIOSH) and outlined in EPA-RTPs Industrial Hygiene Program, administered and managed by the SHEM Branch.

Immediate Medical Attention

Employees are trained to contact 911 and notify the Security Desk to help manage information flow and provide direction to appropriate emergency responders. The on-site Federal Occupational Health (FOH) Clinic nurse can also be notified to respond.

General Injuries and Illnesses

An employee's immediate supervisor must be informed of any safety and health incident and the supervisor will contact the SHEM Branch for an investigation and follow-up, to include any chemical exposure evaluations. Follow-up is conducted to minimize the potential of that incident occurring again.

Chemical Exposure Reports

The ORD SHEM Branch, in coordination with the FOH Occupation Health Physician, will determine if a chemical over-exposure has occurred. The FOH clinic can take clinical samples to assess Biological Exposure Indices (BEIs) for some chemicals

4) Describe institutional programs or methods used to track and evaluate safety-related workplace incidents, including injuries, exposures, accidents, etc. Include the frequency of such assessments. [*Guide*, pp. 18-19]

OSHA Logs

All employers are required by law to report all OSHA-recordable injuries and illnesses. These logs are maintained by the SHEM Branch and reported to the Department of Labor annually. Follow-up investigations are required for all recordable injuries. The definition of a recordable injury is:

- Any work-related fatality.
- Any work-related injury or illness that results in loss of consciousness, days away from work, restricted work, or transfer to another job.
- Any work-related injury or illness requiring medical treatment beyond first aid.
- Any work-related diagnosed case of cancer, chronic irreversible diseases, fractured or cracked bones or teeth, and punctured eardrums.
- There are also special recording criteria for work-related cases involving: needlesticks and sharps injuries; medical removal; hearing loss; and tuberculosis.

Occupational Medical Surveillance Program (OMSP)

OMSP provides a mechanism for the ongoing and systematic collection, analysis and interpretation of health data to improve employee health and safety. The FOH is located on-site and staffed by two full-time Registered Nurses and one part-time Occupational Health physician. All laboratory and field staff are eligible for the OMSP which includes a baseline medical exam and blood tests, annual exams, post-exposure exams, and exit exams following Agency separation. OMSP works in concert with the SHEM Branch in identifying employees that may have chemical, biological, and/or physical hazards that may need to be assessed.

Online Reporting of Unsafe Working Conditions

All RTP employees can anonymously report any unsafe working condition via the RTP@Work intranet site. The anonymous form is immediately sent via automated email to numerous health and safety employees on-site to address concerns.

Semi-annual SHEM Safety Audits

Comprehensive safety audits are conducted by the SHEM Branch twice per year. This includes a "floor-to-ceiling" inspection of all laboratory, office, and animal areas. Findings are released to all employees and action is required to mitigate findings.

Recurring Industrial Hygiene Exposure Monitoring

Employee exposure monitoring is conducted for a variety of substances and an established re-sampling frequency is determined based on exposure results. In most cases, substances (i.e., isoflurane, formaldehyde) are re-sampled every two years due to well-controlled conditions (i.e., used in fume hood/BSC) and low concentrations. Industrial Hygiene resampling frequency criteria is based on industry guidance provided by multiple scientific organizations (ACGIH, AIHA,

NIOSH) and outlined in EPA-RTPs Industrial Hygiene Program, administered and managed by the SHEM Branch.

ii. Standard Working Conditions and Baseline Precautions

The following section pertains to the Occupational Health and Safety Program for all personnel associated with the animal care and use program. Specific information regarding the use of hazardous agents is included in **subsection** *iii* below.

- Medical Evaluation and Preventive Medicine for Personnel [Guide, pp. 22-23] Note: Include blank forms used for individual health assessment as Appendix 6.
 - a) Describe who (e.g., personnel assigned to job/task categories in I.A.2.b.i.2) above) receives personal medical evaluation as a component of individual risk assessment. Describe who are *not* included and/or exempted from personal medical evaluation. *Note:* Do not include the names of personnel.

All federal employees are eligible for EPA's OMSP. As required by legal contract, all on-site contract employees are required to maintain the same medical monitoring requirements as their federal counterparts. No RTP employee, regardless of employment type, is dismissed/exempt from medical monitoring. Appendix 6 includes the EPA's OMSP examination forms and the Duke Health forms used by both the animal care contractor and the veterinary contractor.

EPA Personnel and Student Contractors

The SHEM Branch seeks to ensure the safety of employees by leading and managing a range of safety, health, and environmental management programs. All laboratory and field workers are encouraged to participate in the OMSP that consists of a baseline examination (physical and blood test) which establishes a reference for subsequent annual examinations. Employees working on approved Health and Safety Research Protocols (HSRPs) must participate in the medical surveillance program. Following each examination, the employee meets with the occupational physician to discuss test results.

The program is designed to detect changes in the health status over time resulting from occupational exposures.

Animal Care Staff (contract employees)

Upon employment, every contract employee is required to undergo an initial and subsequent annual health checks. Frequency of

scheduling is determined by area of work and in consultation with an occupational health physician (Duke University Occupational Health).

<u>Attending Veterinarian (contract employee)</u>

Drs Jarrell and Sun receive annual physical examinations with an outside occupational health physician (Duke University Occupational Health). Testing performed is the same as those listed for the animal care staff. The occupational health physician sends the AV a health recommendation report which lists the type of examination, the physician's summary report, and any recommendations or restrictions.

Additional back up veterinary care may be provided by SoBran, Inc. The occupational health program for SoBran, Inc animal care personnel is administered through NowCare Health and Safety.

IACUC Community Representative

The IACUC Community Representative is given the option to receive a similar annual physical examination with a health physician of his/her choosing if he/she participates in activities involving direct animal or vivarium contact.

Other Employees

Visiting scientists, post-doctoral scientists, etc., are subject to the same medical program as are EPA employees. The only difference is that the program is administered by their respective employers rather than EPA.

b) Describe provisions for allowing an individual (following completion of individual health and job related risk assesments) to decline participation in all or part(s) of subsequently available medical and preventive medicine components of the institutional program, e.g., vaccinations, physical examinations, respiratory protection, as applicable. Provide an estimate (percentage) of personnel associated with the animal care and use program that have declined participation in the medical evaluation program.

Note: Do not include names of the personnel

EPA-RTPs OMSP is an exposure driven medical monitoring program. Except for respirator users, almost all job classifications do not require employees to enroll in the OMSP. However, due to the nature of work conducted at RTP, larger employee population, and an approved budget, the SHEM Branch allows and encourages all laboratory and field employees to participate in medical monitoring, even if there is no regulatory requirement. This is a conservative

measure that has historically been followed at RTP. For exact OMSP enrollment criteria, please refer to Appendix 6.

Respiratory Protection: Per OSHA 29CFR1910.134, employees that wear respirators fall into two categories: 1) required respirator use; and 2) voluntary respirator use. Most animal research employees are voluntary users for allergen purposes. Required use is only needed when hazardous conditions exist during work. All hazards are controlled via engineering controls and do not exceed the occupation exposure limit or action limit that would trigger the required use of a respirator. A respirator would be the last line of defense and not seen as an acceptable practice by the SHEM Branch. If a required-use employee was unable to pass a fit test, or be medically cleared, they would be able to wear a powered air purifying respirator (PAPR), that is a positive pressure respirator hood that does not require medical clearance or fit testing. If the employee refused to wear a respirator or PAPR when it was required, they would not be allowed to participate in that task.

Voluntary-use is used to minizine allergens, dust, etc. but is used on a voluntary basis and is not legally required. Voluntary use of filtering face-piece respirators (dust masks) do not require any medical monitoring or fit testing.

<u>Vaccines:</u> Per OSHA 29CFR1910.1030 makes the Hepatitis B vaccine and prophylaxis available at a reasonable time and place for any employee with potential exposure to bloodborne pathogens. These are available on-site through the FOH.

c) Describe provisions for assuring confidentiality of medical information.

All medical information is protected under Health Insurance Portability and Accountability Act of 1996 (HIPPA). The collection and use of medical information are authorized by 5 U.S.C. 7901 (Health Services Programs) and 20 U.S.C 657 (Occupational Health and Safety; Record Keeping). Employees providing any medical information to the FOH is voluntary. All personal identifiable information is collected and safeguarded by the FOH. The only information the SHEM Branch receives from FOH is a medical clearance statement from the Occupational Health physician that approves or disapproves specific job-related duties (i.e., respirator, emergency response, field work, noisy operations, etc.)

The FOH is responsible for recordkeeping and safeguarding patient information.

d) Describe safety considerations for individuals with incidental exposure to animal care and use (e.g., contractors, personnel working in open laboratories).

The animal suite and animal laboratories are physically seperated from non-animal areas (i.e., labs and offices) and have restricted key card access. All employees that could have incidental exposure to animals are required to have animal barrier training before they get access to animal areas. Depending on specific job duties, additional trainings may be (and are likely) warranted. When entering the animal suite, disposable PPE is required to reduce incidental exposures. Additionally, when working in animal areas, the ventilation is designed to allow for more air changes per hour and pressure in relation to other spaces is engineered to eliminate incidental exposure. Finally, all research projects are reviewed prior to work to identify any potential hazards or exposures.

In the event of an accident, the Security Desk is contacted, and they notify the appropriate emergency responders. The on-site Federal Occupational Health (FOH) Clinic nurse can also be notified to respond.

- **e)** Describe general features of the medical evaluation and preventive medicine programs, within the context of work duties, including:
 - pre-employment/pre-assignment health evaluation,
 - medical evaluations (including periodicity),
 - diagnostic tests (e.g., for tuberculosis),
 - precautions for working with potentially hazardous species (e.g., nonhuman primates, sheep, venomous species)
 - immunization programs, and
 - procedures for communicating health related issues.

Research Staff: The Federal Occupational Health (FOH) Clinic is operated by licensed full-time occupational health personnel. Enrolled employees must have all medical examinations and consultations relating to their employment conducted under the direct supervision of the contracted Occupational Health physician. A baseline examination consists of a complete physical with a Comprehensive Metabolic Panel to establish a reference for subsequent examinations. Employees working on approved HSRPs are encouraged to participate in the OMSP and receive an annual physical regardless of the amount of time they spend within the laboratory. After each examination, employees will meet with the Occupational Physician to discuss test results. Employees may

request that the physician's findings be sent to their personal physicians.

Enrollment in the OMSP is initiated by the first-line supervisor through the SHEM Branch. Supervisors must notify the SHEM Branch whenever a new employee starts to work and indicate whether that individual should be enrolled in the OMSP. Supervisors should also notify the SHEM Branch when an employee is going to leave EPA-RTP, so that an exit physical examination can be arranged before the last day of service.

Notification of Medical-Monitoring Results:

After consultation/examination, the SHEM Branch receives a written clearance statement from the examining physician, which includes the following:

- •Recommendation for medical follow-up
- •Any medical condition, not necessarily related to the exposure, that may place the employee at increased risk from future hazardous material exposures in the work place
- •A statement that the physician has informed the employee of the consultation/examination results and any medical condition that may require further examination or treatment

The physician's written opinion shall not reveal specific findings of diagnoses unrelated to occupational exposure. Medical monitoring records are kept on file in the FOH Clinic.

The physician notifies the SHEM Branch if there are signs of a disorder which may be caused by occupational exposure to a workplace contaminant. A SHEM representative will inspect the area, investigate the nature of work, and confer with the physician, employee, and employee's supervisor. If a hazard exists, corrective action will be taken immediately to reduce the hazard to an acceptable level.

Animal Care and Veterinary Staff (contract employees): Upon employment, every contract employee is required to undergo an initial baseline medical evaluation followed by at least annual medical evaluations. Frequency of scheduling is determined by area of work and in consultation with an occupational health physician (Duke University Occupational Health). Each physical consists of the following:

- Blood test
- Urinalysis
- •Medical and occupational history and substance exposure survey.

- Audiometry
- Pulmonary function
- •Additional tests as determined by a physician specializing in industrial medicine and hygiene

(See Appendix 6 for medical evaluation forms)

Any pathogenic problems encountered in the course of routine sampling are recorded on the employee's health record which is maintained at the occupational health clinic (in order to protect patient-doctor confidentiality). The attending occupational physician sends the employee a summary report including the results of all testing. The attending occupational physician sends the contract project manager a Health Recommendation Report which lists the type of examination and any recommendations or restrictions.

An employee file is maintained on-site for every employee. Each file includes the most recent Health Recommendation Form as well as any reports of job-related injury or illnesses. In addition, we emphasize to each employee the health hazards inherent in laboratory animal support services, such as allergies and possible exposure to zoonotic diseases.

RTP does not house any species currently thought to be significantly hazardous (e.g. sheep, primates).

Special precautions or procedures for personnel handling hazardous chemicals or infectious agents are addressed specifically in individual Health and Safety Research Protocols (HSRPs), reviewed and approved by Safety and Health management personnel.

f) Describe any other entities that provide medical services (e.g., emergency care, after-hours care, special medical evaluation, contracted services). Include a brief description of their credentials and/or qualifications, and how these entities remain knowledgeable about animal- or institution-related hazards and risks.

There are a number or urgent care and major hospitals that are experienced with animal and institutional related hazards and risk. Duke University and UNC-Chapel Hill have associated hospitals within 12 and 14 miles, respectively from RTP.

2) Personnel Training Regarding Occupational Health and Safety [*Guide*, p. 20]

Describe general educational program(s) to inform personnel about:

- allergies,
- zoonoses,
- personal hygiene,
- physical injuries in animal facilities (e.g., noisy areas, large quantities of chemicals such as disinfectants, ergonomics) or species used (e.g., nonhuman primates, agricultural animals),
- other considerations regarding occupational health and safety.

Include in the description a summary of the topics covered, including:

- Entities responsible for providing the training
- Frequency of training or refresher training

Note: Do not include special or agent-specific training for personnel exposed to experiment-related hazardous agents; this will be provided in **Section iii.3** below.

Safety and health training occur on more than one level. All new employees are required to attend the Initial Safety, Health, and Environmental Management (ISHEM) training class within the first month of employment at EPA-RTP. It is designed to familiarize the new employee with proper, safe work practices and rules of the facility. The course is an 8-hour training course, with 50% of the course tailored to occupational safety and health. Annual refreshers on this training are required. Following are the topics covered:

Emergency Procedures

Phone numbers

Alarms

Evacuation procedures

Fire extinguishers

Safety showers and eye wash stations

Accident reports

Occupational Medical Surveillance and Laboratory Animal Research

Overview

Physicals

Requirements

Laboratory Animal Allergy

Work Practices and Engineering Controls

Visitors

Working alone

Field Work

Unattended operation

Animal handling, to include zoonoses and allergies

Safety glasses/shoes

Personal protective equipment

Fume hoods/Biological safety cabinets

Personal Hygiene

Smoking

Eating

Alcohol and drugs

Housekeeping

Medical monitoring

• Hazardous Materials Management

Environmental Management Systems

Flammables/combustibles

Lasers

Radiation

Toxins

Compressed gases

Explosive / unstable chemicals

Cryogens

Storage

All in class SHEM trainings are conducted by SHEM staff that are credentialed in various health, safety, and environmental certifications. Following the above training events, the supervisor assumes responsibility for laboratory-specific safety training that includes the hazardous chemicals being used in that lab, hazards presented by the animals, and other pertinent safety and health training.

Finally, ARPO staff provides training on animal handling, zoonoses, bites and allergies, surgical techniques, and other topics, all of which include pertinent safety and health information.

3) Personal Hygiene [Guide, p. 20; Ag Guide pp. 4-5]

a) List routine personal protective equipment and work clothing provided and/or required for animal care personnel, research and technical staff, farm employees, etc.

All research personnel entering the animal facility must wear a disposable lab coat and shoe covers. A surgical face mask and nitrile gloves are required when entering an animal holding room. Additional personal protective equipment (PPE) such as chemical resistant coveralls, particulate respirator, full or half-face air purifying respirators or Powered Air Purifying Respirator (PAPR) may be required by the SHEM Branch when working with the animals. PPE is used as a last line of defense.

All contractor animal care staff are provided with two-piece scrub suits and steel-toed safety shoes. Head covers, face masks, shoe-covers, disposable lab coats and Tyvek coveralls, nitrile gloves, eye and hearing protection, face shields, and respirators are available for use.

b) Describe arrangements for laundering work clothing.

All scrub suits are laundered on-site within the animal facility (Bldg. A). The laundry facilities are located on the first floor between dirty cage wash and a clean entry space.

c) Describe provisions and expected practices for washing hands, showering, and changing clothes, including instances where work clothes may be worn outside the animal facility.

Shower, locker, sink, and change facilities are provided for animal care personnel in the Building A vivarium. Under normal circumstances work clothes are not worn outside the facilities except by designated staff to remove non regulated trash to the dumpsters and regulated trash to the NIEHS incinerator. In the event of a building emergency, animal care staff will wear work clothes outside the facilities.

Showers, lockers and change facilities on the 5th floor of A wing are available to any staff member should they be needed.

d) Describe policies regarding eating, drinking, and smoking in animal facilities.

The following is the SHEM policy on eating, drinking, and smoking: "Laboratory personnel may not eat, drink, chew gum, carry cigarettes or tobacco products, smoke, and/or apply cosmetics while in a laboratory. This rule, in conjunction with good personal hygiene practices such as washing hands, arms, and face, reduces the involuntary ingestion and cross-contamination of hazardous chemicals. Additionally, food or drink is prohibited in the service corridors."

This policy also applies to anyone working in the animal holding rooms, procedure rooms or hallways.

For the ACS/AHS, eating and drinking are strictly prohibited in animal housing areas and hallways leading to these areas. Eating

and drinking are permitted in the Building A break room (A285), conference room (A284) and the project office suite (A290).

Smoking is prohibited throughout all the buildings and is allowed only in outdoor designated smoking areas on campus.

4) Standard Personnel Protection [Guide, pp. 21-22]

a) Describe facility design features, equipment and procedures employed to reduce potential for physical injury inherent to animal facilities (e.g., noisy areas, large quantities of chemicals such as disinfectants, ergonomics) or species used (e.g., nonhuman primates, agricultural animals).

Engineering Controls: Our primary engineering exposure control is general ventilation and local exhaust ventilation. General ventilation is specifically designed to provide filtered fresh outdoor air at specific temperature and humidity requirements into the space. Based on the function of the room, air changes per hour are calculated and maintained. All surgical rooms have supply air at ceiling height with exhaust diffusers at floor and bench height to ensure effective capture of anesthetic gases (i.e., isoflurane), since they are heavier than air. At the entrance of the animal facility, airlocks prevent the contamination from entering or exiting the animal areas. Local exhaust design includes chemical fume hoods, biological safety cabinets, active scavenging systems, and snorkel hoods.

<u>Noise</u>: Any noisy areas (i.e., cage washing) are physically seperated from any animal areas. Shielding and distance are the two control methods for noise.

<u>Chemicals</u>: All chemicals must be stored in compliance with SHEM's chemical hygiene procedures, which outline chemical segregation and storage requirements for chemical users.

<u>Ergonomics</u>: Any furniture purchase (i.e., lab or desk chair) must have the approval of the SHEM Branch and RTP Architect to ensure it meets appropriate ergonomic principles (i.e., 5-point caster base, lumbar support, adjustable seat pan depth, adjustable arm rests, etc.). Also, the SHEM Branch and OARM FSB provide ergonomic assessment upon request and provide a written report with recommendations.

RTP does not house any species currently thought to be potentially hazardous – no sheep, non-human primates, etc.

b) Describe likely sources of allergens and facility design features, equipment, and procedures employed to reduce the potential for developing Laboratory Animal Allergies (LAA).

Likely sources include direct handling of animals during husbandry and exposure to bedding during cage cleaning. Most likely exposure source is dermal (including bites) and inhalation exposure.

Potential exposure is controlled by utilizing the hierarchy of controls which include engineering controls, administrative work practices and PPE.

<u>Engineering</u>: Animals are stored in individual holding rooms that provide a physical barrier with separate ventilation. Procedures are conducted in biological safety cabinets when possible. Caging is dumped in dirty cage wash or in a dump station. Dirty cage wash has an elevated air exchange rate.

Administrative Work Practices: include various training classes (ISHEM, annual SHEM trainings, Rat/Mouse 101, etc.) and following standard operating producers for safe handling. Additionally, all scrubs worn by animal care staff are laundered onsite and not distrusted to other parts of the campus. PPE: appropriate PPE (scrubs, lab coats, gloves, surgical mask or N95).

Exposure monitoring for LAA (rat n 2 and mus m 1) is available to assess LAA by the SHEM industrial hygienist.

c) Describe likely sources of zoonoses and facility design features, equipment, and procedures employed to reduce potential exposure to zoonoses.

Likely sources of zoonoses are from the fish or rodents.

The aquatics facility screens for fish pathogens and includes potential zoonoses in the panel. There have been no zoonoses flagged in recent years, but staff are still expected to take appropriate precautions like wearing PPE, washing their hands, etc.

Rodents are received from commercial vendors and must meet specific biosecurity requirements. Most human pathogens are not allowed to enter the facility. Potential zoonoses endemic to the human population, like Staph aureus, are not barred. Staff are expected to take appropriate precautions to avoid either acquiring these pathogens from the animals or passing them to the animals. Precautions would include basic hygiene, wearing PPE and other common-sense practices.

Very few lagomorphs are brought into the facility; these also meet biosecurity requirements and staff is still expected to wear PPE, practice basic hygiene, and exercise common sense.

d) Describe the procedures for the maintenance of protective equipment and how its function is periodically assessed.

RTPP uses NIOSH validated disposable PPE. Gloves, N-95 respirators, lab gowns, and ear plugs are all disposed of after the work shift or earlier, if excessively soiled, torn, or otherwise degraded. All safety glasses and goggles are ANSI-approved. Eye protection is validated during semi-annual safety inspections.

e) Respiratory Protection

i) Describe situations where respiratory protective equipment is available or required, such as cage washing facilities, feedmills, etc.

With engineering controls in place (i.e. chemical fume hoods, biological safety cabinets, and general exhaust ventilation) respiratory protection is generally not required for federal research staff or animal care staff. Disposable N-95 filtering face-pieces are available for those who want them, but their use is voluntary. Voluntary users are required to sign the OSHA Appendix D Voluntary Use. Copies are retained by the SHEM Branch for Federal employees.

ii) Describe programs of medical clearance, fit-testing, and training in the proper use and maintenance of respirators.

The SHEM Branch manages the Respiratory Protection Program that outlines medical clearance, fit-testing, training, and storage and maintenance of respirators for EPA-RTP federal and animal care staff employees. Copies of the Respiratory Protection Program are available for employees electronically via the intranet and hard copy in the SHEM Office.

iii) Describe how such respiratory protective equipment is selected and its function periodically assessed.

A Job Hazard Assessment is conducted to determine workplace conditions. Exposure monitoring is also conducted if needed to characterize exposure levels and respirator selection. Based on the risk (i.e., sample results), respirators are chosen based on their assigned protection factor to protect again airborne concentrations. It is best practice to control exposures to as low as achievable and respirator use is not typically required.

N95 respirators are readily available to all research and animal care staff as an alternative to surgical masks. Employees working on the dirty side of the cage wash areas are strongly encouraged to wear N 95 respirators.

f) Heavy Equipment and Motorized Vehicles

i) Provide a general list of the types of cage-processing equipment used, such as rack/cage washers, tunnel washers, robotics, and bulk autoclaves. Describe training programs, informational signage, and other program policies designed to ensure personnel safety when working with such equipment.

Note: Details of specific equipment installed in animal facility(ies) are to be provided in **Appendix 15** (Facilities and Equipment for Sanitizing Materials).

All new employees are trained to recognize and utilize ergonomic concepts during the ISHEM training course. Employees learn to notify their supervisor or SHEM manager to request an ergonomic assessment if they experience musculoskeletal discomfort that may be related to physical conditions in the workplace. Further, upon reporting to their duty station, the employee's supervisor is required to provide on-site safety training on hazards specific to their area.

All animal care staff are instructed bi-annually (every 6 mos.) on the safety procedures necessary when working around the rack/cage washers and the walk-in sterilizer. This instruction takes place in the cage wash areas and includes a hands-on demonstration of what to do in the event of entrapment. Large DO NOT ENTER signs are positioned outside the rack washers as a reminder of the potential danger of this equipment.

ii) List other heavy equipment such as scrapers, tractors, and farm machinery (manufacturer name, model numbers, etc. are not necessary). Describe training programs, informational signage, and other program policies designed to ensure personnel safety when working with such equipment.

Note: If preferred, this information may be provided in a Table or additional Appendix.

There are no scrapers, tractors, farm machinery or similar heavy equipment in use.

iii) If motorized vehicles are used for animal transport, describe how the driver is protected from exposure to hazards such as allergens or zoonoses and decontamination methods employed. Also describe instances where vehicles may be shared between animal and passenger transport.

Vehicles are not shared between animal and passenger transport.

When the dedicated van is used to move animals across campus or to local institutions, the animals are transported in secured shipping containers with filter paper in place to prevent the spread of pathogens.

Individuals transporting the animals are expected to wear the same PPE as they would wear working in the vivarium. Decontamination happens after each use. Procedure is as follows: Cargo area is first swept, Virkon solution is applied, and allowed to air dry; contact time is approximately 15 minutes.

g) Describe safety procedures for using medical gases and volatile anesthetics, including how waste anesthetic gases are scavenged.

The use of anesthetic gasses occurs in a primary engineering control with passive scavenging when possible. When the procedure requires a bench-top and a primary engineering control cannot be used, passive scavenging is used. Waste anesthetic gas is monitored on a set frequency (per SHEM Industrial Hygiene Program) to monitor employee concentrations, which are historically low and well-controlled via ventilation engineering controls.

iii. Animal Experimentation Involving Hazards [Guide, pp. 20-21]

1) List, according to each of the categories noted below, hazardous or potentially hazardous agents currently approved to be used in animals that are or will be maintained for more than a few hours following exposure. If the hazardous agent cannot be listed by name for security/proprietary reasons, identify it by the general category of agent and level of hazard. Note: If preferred, this information may be provided in a Table or additional Appendix.

a) Biological agents, noting hazard level (CDC Biohazard Level, Directive 93/88 EEC, CDC or USDA/DHHS Select Agent, etc.). Examples may include bacteria, viruses, viral vectors, parasites, human-origin tissues, etc.

RTPP no longer has any investigators working with biological agents

b) Chemical agents, *noting general category* of hazard (toxicant, toxin, irritant, carcinogen, etc.). Examples may include streptozotocin, BrdU, anti-neoplastic drugs, formalin, etc.

Hazardous Agent Used	Hazard Category
1,2-Dinitrobenzene	Toxicant
1,3-Butadiene	Carcinogen, mutagen
1,4-Diisopropylbenzene	Irritant, possible reproductive toxicant
1-Bromopropane	Carcinogen, reproductive toxicant
5-Bromo-2'-Deoxyuridine (BrdU)	Mutagen, reproductive toxicant
5-Ethynyl-2?-Deoxyuridine (EdU)	Mutagen, reproductive toxicant
6:2 FTOH	xenoestrogen
6-N-Propyl-2-Thio-Uracil (PTU)	Carcinogen
Acetaldehyde	Carcinogen
Aconitine	Irritant
Acrolein	Irritant
Ammonium Perchlorate	explosive
Bisphenol A	Irritant, sensitizer, reproductive toxicant
Bisphenol C	Possible Irritant, sensitizer, reproductive toxicant
Bromoform	Toxicant
Tribromonitromethane	Toxicant, irritant, sensitizer
Carbon Tetrachloride	Toxicant, irritant
Celecoxib	Reproductive toxicant
Trichloronitromethane	Toxicant, irritant
Cylindrospermopsin	Mutagen, toxicant
Cyprodinil	Sensitizer

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Dexamethasone	Reproductive toxicant
Dibromoacetic Acid	Irritant
Dibromonitromethane	Acute toxic, irritant
Dichloroacetic Acid	Carcinogen, irritant
Dichloromethane	Carcinogen, irritant
Diiodoacetic Acid	Acute toxic, corrosive
Dipropyl Phthalate	Reproductive toxicant
Formaldehyde	Irritant, sensitizer, mutagen, carcinogen
Hexafluoropropylene oxide dimer acid	Possible teratogen
Indomethacin	Toxicant
Inorganic Arsenic	Carcinogen, irritant, toxicant
Iodoacetonitrile	Irritant
Triiodonitromethane	Suspected carcinogen and reproductive toxicant
MCLA	Not enough data to
WELA	determine
MCLF	Toxicant
MCLR	Toxicant
Microcystin-Leucine-Tryptophan	Microcystin is a toxicant
Microcystin-Leucine-Tyrosine	Microcystin is a toxicant
Microcystin-Arginine-Arginine	Microcystin is a toxicant
Microcystin-Trytophan-Arginine	Microcystin is a toxicant
Microcystin-Tyrosine-Arginine	Microcystin is a toxicant
Microcystin LR	Toxicant, sensitizer
Monochloroacetic Acid	Irritant
Perfluoro(4-methyl-3,6-dioxaoct-7-ene) sulfonyl	Irritant
Nafion byproduct 2	Suspected reproductive toxicant
Oleic Acid	Flammable, probable irritant, possible carcinogen and mutagen
Oxyfluorfen	Herbicide, irritatant
Ozone	Toxicant, sensitizer
Prochloraz	Pesticide, acute oral toxicity
Perfluorobutane Sulfonate	Irritant
Perfluorohexanoic Acid	Irritant
Perfluorohexanesulfonic Acid	Irritant
Perfluorononanoic Acid	Corrosive, irritant
Perfluorooctanoic Acid	Carcinogen, irritant, reproductive toxicant
Perfluorooctanesulfonic Acid	Irritant
Phenolphthalein	Carcinogen, mutagen,
<u>'</u>	reproductive toxicant

Picric Acid	explosive
Sodium Perchlorate	Toxicant
Tribromoacetic Acid	Irritant
Trichloroethylene	Carcinogen, toxicant
Urethane	Carcinogen, irritant, toxicant

c) Physical agents (radiation, UV light, magnetic fields, lasers, noise, etc.).

Fish racks have UV lights for water disinfection

2) Experiment-Related Hazard Use [Guide, pp. 18-19; See also Chapters 2 and 3 in Occupational Health and Safety in the Care and Use of Research Animals, NRC 1997].

Note: Written policies and standard operating procedures (SOPs) governing experimentation with hazardous biological, chemical, and physical agents should be available during the site visit.

a) Describe the process used to identify and evaluate experimental hazards. Describe or identify the institutional entity(ies) responsible for ensuring appropriate safety review prior to study initiation.

<u>Hazard identification and risk assessment</u>: Systems are in place that contribute to the identification and assessment of "experimental" hazards and ensure the appropriate monitoring activities take place. These are as follows: 1) Job Hazard Assessments (JHAs); 2) Health and Safety Research Protocols (HSRPs); 3) Animal Care and Use Protocol review (ACUP), and; 4) chemical procurement safety and health reviews.

For any substance that is experimental and/or of unknown toxicity, it is treated as a "worst-case" scenario and the most conservative precautions are taken. It is the SHEM Branch and Health and Safety representative on the ORD Health IACUC that are responsible for ensuring appropriate safety review prior to study initiation.

1) (JHAs): These are performed to determine potential hazards or potential hazards. A literature review of all potential hazards from compound use is conducted to better characterize potential hazards during experimental use.

- 2) HSRPs: Any employee using a substance that is unknown or experimental, they must submit a HSRP that is reviewed by a committee of industrial hygienists, environmental compliance officers, and other safety personnel prior to granting employees approval to use the hazardous substance. Information required on HSRPs include: 1) description of the study highlighting hazardous processes; 2) authorized personnel and their training and experience; 3) experimental chemical and other-related dangerous agents and literature on potential toxicity; 4) location(s) of work and processes; 5) waste disposal methods, and; 6) emergency response.
- <u>3) ACUP:</u> The ACUP review process includes a section that identifies chemicals administered to animals and is reviewed by the ORD safety and health manager who is a permanent member on the IACUC. This experimental agent would also be identified in the HSRP.
- 4) Chemical Procurements: Safety Review and Approval: All chemicals ordered by investigators must be approved by the SHEM Branch. The procurement system is set up such that all chemical orders are automatically routed to the safety and health reviewer who reviews the order to ensure that any hazardous chemicals are included on a HSRP. If proper documentation and controls are not in place for highly hazardous substances, the safety and health reviewer withhold approval until the documentation and controls are in place.
- b) Describe how risks of these hazards are assessed and how procedures are developed to manage the risks. Identify the institutional entity(ies) responsible for reviewing and implementing appropriate safety or containment procedures.

same as above

c) Describe the handling, storage, method and frequency of disposal, and final disposal location for hazardous wastes, including infectious, toxic, radioactive carcasses, bedding, cages, medical sharps, and glass.

Hazardous waste:

Hazardous wastes are collected directly from the laboratory on an asneeded basis. Wastes that will be bulked or co-mingled into 55 gallon drums (flammable solvents and non-regulated liquids) will be bulked within 3 days in the central accumulation areas. Wastes that will be labpacked are transported to the on-site permitted waste handling facility that is shared with the National Institution of Environmental Health Sciences (NIEHS. The NIEHS campus is contiguous with the EPA campus, though animal facilities and programs are independent.). Any bedding or carcasses that are also contaminated with hazardous wastes are also stored at this facility in cold storage until shipment for disposal. EPA and NIEHS wastes are managed separately and never combined. Hazardous wastes may be stored onsite for up to 1 year prior to shipment for disposal. Our preferred method of disposal of hazardous wastes is incineration. Hazardous waste is shipped for final disposal with Veolia Environmental Services to incinerators located in Port Arthur, TX and Sauget, IL. We will only ship wastes to landfill as a last resort. We generally have hazardous waste shipments once per quarter.

Infectious wastes:

Currently there are no infectious agents in use in the RTTP. Should any come into use, the procedure below would be followed.

Infectious wastes from the laboratories are collected by Chemical Services upon request from the laboratories and transported to the onsite med-path incinerator shared with NIEHS. Deliveries of wastes to the incinerator by chemical services staff are generally done twice a month. Animal carcasses and bedding from infectious agent research will also be incinerated at the same shared med-path incinerator. Carcasses and bedding are clearly marked and handled in a separate waste stream from regular vivarium waste. Animal Care Staff work with Chemical Services Staff to ensure timely incineration of carcasses. Bedding and caging are sterilized in A580 (Decontamination) prior to returning to dirty cage wash for cleaning and disposal.

Radioactive wastes:

Currently there are no radioactive materials in use in the RTTP. Should any come into use, the procedure below would be followed.

Animal carcasses injected with radioactive materials are picked up by Chem Services upon request and taken to the waste area in A-167A where they are stored in a freezer prior to disposal offsite or incineration at NIEHS in a radiation dedicated incinerator. Anything else that would become contaminated is double bagged and brought to A-167 by Chemical Services upon request for disposal or incineration. These wastes must also be picked up within three business days of the initial request. Radioactive wastes that are shipped offsite for disposal are shipped either by Veolia Environmental Services or other waste broker under a separate contract.

Glassware from labs is either recycled or shipped for disposal depending on glass type

d) Describe aspects of the medical evaluation and preventive health program specifically for personnel potentially exposed to hazardous agents.

Occupational Medical Surveillance Program (OMSP)

OMSP provides a mechanism for the ongoing and systematic collection, analysis and interpretation of health data to improve employee health and safety. The FOH is located on-site and staffed by two full-time Registered Nurses and one part-time Occupational Health physician. All laboratory and field staff are eligible for the OMSP which includes a baseline medical exam and blood tests, annual exams, post-exposure exams, and exit exams following Agency separation. OMSP works in concert with the SHEM Branch in identifying employees that may have chemical, biological, and/or physical hazards that may need to be assessed.

Contractors are responsible for maintaining their own medical surveillance program that is equivalent or more conservative than EPAs.

3) Hazardous Agent Training for Personnel [*Guide*, p. 20] Describe special qualifications and training of staff involved with the use of hazardous agents in animals.

Safety and health training occur on more than one level. All new employees are required to attend ISHEM training class within the first month of employment at EPA-RTP which goes into detail on hazards associated with animal research and care. Various animal handling and job-specific trainings are also conducted.

4) Facilities, Equipment and Monitoring [Guide, pp. 19-20]

a) Describe locations, rooms, or facilities used to house animals exposed to hazardous agents. Identify each facility according to the hazard(s) and containment levels (if appropriate).

Note: If preferred, information may be provided in a Table or additional Appendix.

The animal suite is in Building A and physically seperated from all non-animal care and research areas. Access into the animal suite is restricted via keycard access. All individual animal holding rooms have researcher contact information and restricted keycard access. Following risk assessment initiated by ACUP review, individual animal cages may be labeled with a Chemical Alert Tag (CAT). Chemical

Alert Tags are an animal program specific procedure in place to alert Animal Care Staff and other contract employees in the animal facility of potential hazards created by research processes that involve treating, dosing or exposing animals with a highly hazardous substance. This system uses a CAT to inform employees of existing chemical hazards, ensure emergency contact information is available, and notify employees of necessary PPE requirements. CAT tags are developed and implemented with consultation between the SHEM, researcher, animal care staff, and animal care and use program staff. Additionally, all animal laboratory areas have posted door signs that outline laboratory point of contacts and their contact information, and what the required PPE is before entering the laboratory

b) Describe circumstances and conditions where animals are housed in rooms outside of dedicated containment facilities (i.e., in standard animal holding rooms). Include practices and procedures used to ensure hazard containment.

Animals requiring quarantine will be placed in the quarantine room in A196A. The quarantine room is designed to be an isolation room that is under negative pressure to eliminate potential spread into other adjacent areas.

The High Hazard suites and decontamination facilities are also available on 5th floor.

Animals treated with hazardous chemicals are often housed in regular holding rooms. These animals will have been evaluated for risk by Safety, Health and Environmental Management and will only be housed in regular holding rooms if the risk is considered minimal. For example, animals exposed to smoke will be housed in ordinary holding rooms. The smoke is a hazard, but the animals do not remain hazardous after the exposure is finished.

c) Describe special equipment related to hazard containment; include methods, frequency, and entity(ies) responsible for assessing proper function of such equipment.

The main form of hazard containment is via our primary engineering controls: chemical fume hoods and biological safety cabinets. The SHEM Branch is responsible for annual certifications and the FSCB is responsible for maintenance outside of the annual certifications. Chemical fume hoods are certified initially using the American Society of Heating, Refrigeration, and Air-conditioning Engineers (ASHRAE) 110 Standard Method: "Method of Testing Performance of Laboratory Fume Hoods." The hoods are then certified annually according to Procedures for Certifying Laboratory Fume Hoods to Meet EPA

Standards by an outside contractor specializing in chemical fume hoods to ensure proper operation and containment capability. Biological safety cabinets are certified upon installment and annually thereafter according to the National Sanitation Foundation (NSF) 49 Standard Method: "Biosafety Cabinetry Certification", which is the international standard for BSC design and testing criteria.

d) Describe the husbandry practices in place to ensure personnel safety, including any additional personnel protective equipment used when work assignment involves hazardous agents.

All animal care staff undergo a variety of health and safety and animal handling classes previously described. All animal care staff are required to wear two-piece scrubs that are laundered on-site. Additionally, when in animal holding rooms, there are required to wear disposable shoe covers and apron that must be removed leaving and before entering another animal holding area. While not a husbandry practice, research requiring the use of CAT notification also requires a meeting between ACS, ARPO and SHEM to discuss safety, husbandry and waste management requirements before initiation of animal work.

- e) Incidental Animal Contact and Patient Areas
 - i) List and describe facilities that may be used for both animal- and human-based research or patient areas, including the policies and procedures for human patient protection, facility decontamination, animal transport through common corridors or elevators, and other personnel protection procedures.

There are no patient areas, nor areas shared for both human and animal research.

ii) Describe any *other* circumstances in which animals or caging equipment are transported in common use corridors or elevators (e.g., have the potential to come in contact with individuals not associated with the animal care and use program), and measures taken to mitigate risks associated with such use.

Animal movement outside of the vivarium varies depending if the movement is to Building A labs or Building B labs. Animals may move back and forth from Building A labs and the Building A vivarium, though specific procedures detailed in a Building A SOP must be followed. These animals do not move through public spaces, and Building A was designed and built to support this use.

Animals moving outside of Building A may not return. Detailed procedures for transport are also outlined in the Building A SOP. The animals are transported in closed caging with filters on carts serving as secondary containment. Transport is limited to less public spaces such as laboratory service corridors and service elevators, rather than out in open public atriums.

B. Program Oversight

- 1. The Role of the IACUC/OB [Guide, pp. 24-40]
 - a. IACUC/OB Composition and Function [Guide, pp. 17; 24-25]
 Please provide a Committee roster, indicating names, degrees, membership role, and affiliation (e.g., Department/Division) as Appendix 7.
 - i. Describe Committee membership appointment procedures.

Committee members are officially appointed by the ORD Health IACUC Institutional Official, Wayne Cascio, Director, CPHEA.

Wayne Cascio as IO was appointed by Chris Robbins, Deputy Administrator for Management for ORD.

ii. Describe frequency of Committee meetings. Note that **Appendix 8** should contain the last two IACUC/OB meeting minutes.

Scheduled IACUC committee meetings occur as follows:

- a. IACUC ACUP (Animal Use Protocol) Review usually every 2 weeks, provided there is quorum
- b. IACUC Business meetings quarterly
- c. IACUC Program Review semi-annually
- d. IACUC Facility Inspections semi-annually
- e. Additional meetings can be called by the chair at any time deemed necessary

See APPENDIX 8: IACUC Quarterly Business Meeting Minutes 9/2019; IACUC Review Meeting Minutes for 9/25/19

iii. Describe the orientation, training, and continuing education opportunities for IACUC/OB members. [*Guide*, p. 17]

Orientation and training of IACUC members consists of the following:

New IACUC members meet individually with the IACUC Administrator and the Chair for basic orientation in their new duties. Orientation covers basic expectations regarding service and attendance at meetings, discussion of what IACUC service entails and how it relates to RTPP as a whole rather than to the science of individuals. Members are encouraged to ask questions both during these meetings, and at any time during their service. During orientation new members are provided with copies of all pertinent regulatory and institutional documents including:

- The Guide for the Care and Use of Laboratory Animals (NRC, current edition)
- The Animal Welfare Act and Regulations
- The Public Health Service Policy on Humane Care and Use of Laboratory Animals
- The U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training
- The AVMA Guidelines on Euthanasia (current edition)
- ORD Health IACUC Research Animal Care and Use Policies/Guidelines
- ORD Health IACUC Operating Procedures for Reviewing a Laboratory Animal Project Review and Supporting Documents – EPA/RTP Campus
- ORD HEALTH IACUC Operating Procedure for Responding to a Possible Incident of Noncompliance or Animal Welfare Concern

Additionally, new members are informally paired with more experienced IACUC members to serve as mentors.

New members are also provided access to IACUC related modules in the AALAS Learning Library. Topics covered include:

- Semiannual Facility Inspection
- Common Compliance Issues
- AVMA Guidelines for the Euthanasia of Animals: 2013 Edition
- Occupational Health and Safety in the Care and Use of Research Animals
- Animal Welfare Act Regulations
- Public Health Service Policy on Humane Care and Use of Laboratory Animals
- Working with Controlled Substances
- 8th Edition of the Guide for the Care and Use of Laboratory Animals (2011)
- Essentials for IACUC Members
- Post-Approval Monitoring
- Ethical Decision-Making in Animal Research

A newly selected chair is oriented to additional IACUC duties and shadows the current chair prior to officially assuming the role of IACUC chair. Formal orientation is provided by the IACUC chair, IACUC Administrator and Director of the Animal Resources Program Office, with specific trainings or readings recommended based on the background and concerns of the new chair. The current chair may also provide a package of written documentation of major events occurring during their tenure and areas of particular on-going concern. Specific materials are also provided on communication with the IO and handling of investigation into possible non-compliance.

All IACUC members are provided with continuing education opportunities such as attendance at workshops provided locally by the North Carolina Association for Biomedical Research (NCABR), OLAW Outreach Webinars, and AALAS Webinars. Some members of the IACUC may also attend the annual PRIM&R conferences, IACUC 101 workshops, or AAALAC sponsored workshops.

b. Protocol Review [*Guide*, pp. 25-27]

A blank copy of your institution's protocol review form should be provided as **Appendix 9**. Also include forms used for annual renewal, modifications, amendments, etc., as applicable.

- i. Describe the process for reviewing and approving animal use. Include descriptions of how:
 - the IACUC/OB weighs the potential adverse effects of the study against the potential benefits that may result from the use ("harm-benefit analysis"),
 - protocols that have the potential to cause pain or distress to animals are reviewed and alternative methodologies reviewed,
 - veterinary input is provided, and
 - the use of animals and experimental group sizes are justified.

Note: Make sure you address each of the items above.

The IACUC usually meets every two weeks to review and approve, require modifications to secure approval, or withhold approval of new research protocols, amendments to protocols, and annual updates/review of current protocols. At RTPP, an animal study or animal use protocol is referred to as an Animal Care and Use Protocol [ACUP; See APPENDIX 9 – Animal Care and Use Protocol (ACUP) Forms]. ACUPs and most related documents are reviewed at convened meetings of an IACUC properly constituted according to 9CFR and PHS policy, and a quorum must be present at the meeting.

ACUP documents (new protocols and amendments) are electronic and stored in the electronic ACUP (ACUP) database. The ACUP review and approval process begins with an investigator completing an online ACUP form (protocol or amendment). Upon completion, the document is reviewed by the investigator's supervisor (Branch Chief (BC)) for scientific merit and support of the Agency's Mission. Upon Branch Chief approval, the item is submitted to the IACUC administrator who then logs the item and assigns it to the next review meeting agenda. Prior to the committee review, ACUP items are screened by the Attending Veterinarian (AV). Questions and concerns during this "pre-screen" process are discussed with the investigator. "Pre-screen" comments or questions are attached to the document as a portable document format (PDF) file if the response is received from the PI prior to the IACUC review meeting. If the response does not arrive prior to IACUC review, the questions are carried over into the review session and will be reflected in the Minutes.

At full IACUC review meetings (FCR), ACUP items are either approved, require modifications to secure approval or approval is withheld. Decisions are by majority vote of the quorum of IACUC members present. A procedure for Designated Member Review (DMR) of documents following FCR is in use. Those documents which are not approved or assigned to DMR are generally reassigned to the next convened IACUC Review Meeting.

Documents which require modifications to secure approval following FCR may, with unanimous vote of the quorum of IACUC members present during the FCR, be assigned to DMR. The Chair assigns at least two Designated Reviewers (DRs). Once the questions raised during FCR are addressed, the DRs may approve, require modifications to secure approval, or request full committee review of documents assigned to them. Designated Members must be in accord on their decisions to approve or the document goes back to FCR. The process for DMR following FCR follows an SOP which was agreed upon by all IACUC members, and which is acknowledged by all new IACUC members when they begin their service.

Documents, usually only simple amendments, can be nominated for Designated Member Review (DMR) outside of FCR. The process is as follows: An IACUC member requests that the AV and the Chair review the document. If both are in agreement that DMR is suitable, the Chair assigns one or more Designated Reviewers (DRs). Upon notification by the IACUC Chair, the IACUC Administrator sends to the full IACUC an e-mail listing the item(s) assigned and the IACUC member(s) designated to review them. A PDF file of each document is attached to the email for review. The full IACUC has 3 business days to respond to the IACUC Chair or IACUC Administrator that they request full committee review. If no requests for full committee review are made, the IACUC Administrator or Chair would

inform the DR(s) that they may review the document. The DR(s) can only approve, request modifications to secure approval or defer the item for full committee review. DRs must be in accord in order to approve a document.

Once the IACUC reviews a document a letter is sent out from the ACUP Agenda by the IACUC Administrator notifying the investigator that the IACUC has reviewed the document and that some decision has been achieved (approval, modification required to secure approval, etc.). If an ACUP requires modifications to secure approval and is reassigned to the next FCR, or is disapproved, a second e-mail message will be generated. This second email, containing the specific items that require clarification by the investigator, will be sent by either an IACUC member or the IACUC Administrator. The investigator responds directly to the e-mail and also makes any required modifications to the electronic ACUP document. If the IACUC has decided to send the document to DMR after the FCR the entire IACUC is informed via e-mail that the changes have been made. The members may then review the changes. Committee Members have 3 business days to request FCR for documents that have gone to DMR following FCR. If no IACUC member calls for FCR, the DRs review the document and may approve, require modifications, or return the document to FCR. The IACUC also may, with unanimous agreement of all IACUC members present during FCR, agree to waive the 3-day period for documents in DMR following FCR.

Items that were reassigned are held for review at the next regularly scheduled meeting and follow the original FCR procedure.

Decisions to withhold approval may be appealed with additional information and clarification. The e-mail correspondence regarding any required modifications is converted to PDF files and attached to the ACUP document.

All research currently performed at RTPP is supported by ORD funds, which are provided by Congressional appropriations, rather than grants. All ACUPs and related documents are submitted to ORD Branch Chiefs (BC) or Division Directors (DD) for review and approval before they are considered for review by the ORD HEALTH IACUC. The approval by Branch Chief or Division Director indicates that the proposal is in support of the Agency Mission and is scientifically sound. The IACUC will still weigh scientific considerations when reviewing a document, but the bulk of scientific merit review falls to the BC or DD.

The scientists working at the RTP campus of the ORD work in support of the Agency Mission of protecting human health and the environment. The first question on the ACUP form inquires how the proposed study will support this mission. The IACUC considers the costs to the animals and weigh them against the benefit to society described in the ACUP.

All ACUP and Amendment forms require thorough descriptions of all procedures to be performed on animals under that protocol, and also require that all animal work be assigned to one of the USDA pain categories. These descriptions and their subsequent categorizations are carefully reviewed by the IACUC. Along with requesting that investigators assign their work to appropriate pain categories, the ACUP form requires that any category D or E work be accompanied by a search for alternatives to the painful or distressing procedure(s), and a justification of why that work is scientifically necessary. This information is also carefully reviewed by the IACUC.

Veterinary input can be solicited by an investigator at any point during the construction or use of an ACUP. Prior to the committee review, ACUP items are usually screened by the Attending Veterinarian (AV). Questions and concerns during this "pre-screen" process are discussed with the investigator. "Pre-screen" comments or questions are attached to the document as a portable document format (PDF) file if the response is received from the PI prior to the IACUC review meeting. If the response does not arrive prior to IACUC review, the questions are carried over into the review session and will be reflected in the Minutes.

The ACUP and amendment forms specifically ask investigators to detail how many animals will be required and to justify the number of animals by including biological, statistical, or regulatory rationale explanations.

ii. Describe the process for reviewing and approving amendments, modifications, and revised protocols. If applicable, include a description/definition of "major" vs. "minor" amendments. Note: If preferred, this information may be provided in a Table or additional Appendix.

Modifications to a protocol are all considered Amendments and would follow the same procedures described for new protocols, above. There is no differentiation of major vs. minor amendments at this time. The IACUC reserves the right to request that extensive changes to a protocol, particularly changes in the goals of a protocol, be submitted not as an Amendment but as an entirely new ACUP.

The RTPP does have a Veterinary Verification and Consultation Policy for changes to anesthesia, analgesia, or sedation. These changes to an ACUP are still considered amendments, but the policy is in place to automatically allow the veterinarian to essentially serve as a designated reviewer. If for any reason the veterinarian questions whether an amendment should be handled by VVC, the veterinarian is always able to send the amendment to FCR for consideration.

- c. Special Considerations for IACUC/OB Review [Guide, pp. 5; 27-33]
 - i. Experimental and Humane Endpoints [Guide, pp. 27-28]
 - Describe the IACUC/OB's review of "humane endpoints," i.e., alternatives to experimental endpoints to prevent or in response to unrelieved animal pain and distress.

Experimental and humane endpoints are handled on a case-by-case basis, with no single set of criteria considered to be suitable for all experiments. Development of these endpoints involves the PI, the AV, and the IACUC. In the ACUP, the IACUC does ask that investigators provided precise definitions of the endpoints they do use, including what clinical or other assessments will be used to determine when an endpoint is reached. The IACUC also asks the investigators to describe the frequency of observation, identify the staff who will be responsible for the observations (and include their training in the personnel table), and state what will happen to an animal when the endpoint is reached.

2) For studies in which humane alternative endpoints are not available, describe the IACUC/OB's consideration of animal monitoring and other means used to minimize pain and distress (e.g., pilot studies, special monitoring, other alternatives).

When it is not possible for humane endpoints to be established before the start of a study, the IACUC will often request pilot work or reports from the investigators in order to establish appropriate endpoints as a study progresses. The AV may ask to be notified when the pilot work takes place so she may observe the procedure. Increased monitoring of study animals is usually expected until endpoints are clearly defined; this heightened monitoring may remain in place for the duration of the study if the IACUC and/or AV consider it necessary.

Other methods of minimizing pain and distress may also be employed: methods of physiologic support like changes in housing, bedding, food and hydration may all be used

3) Identify personnel responsible for monitoring animals for potential pain and distress and describe any mechanisms in place to ensure that the personnel have received appropriate species- and study-specific training.

Each animal care and use protocol asks who will be responsible for monitoring the animals, and all personnel listed on the protocol are reviewed by the IACUC and AV for adequate training for their role in the study.

For studies with high likelihood of adverse effects, the investigators are asked to increase monitoring and provide any necessary intervention. They are also asked to alert the AV.

The AV takes an active role in studies with undefined humane endpoints or expected adverse effects, often observing the study work and frequently checking the study animals.

Animal care staff is also put on alert when studies have increased potential for adverse events.

For studies where no adverse effects are expected, research and animal care staff still monitor the animals. The Animal Health Technician (AHT) is also involved with daily monitoring of the animals. Animal care staff perform twice daily checks of all animals in the facility. Monitoring by research staff is more variable, based on study requirements. Animal care staff and the AHT are evaluated for competency in animal care and handling by both their contract management and also the AV. Training and retraining is provided as necessary

ii. Unexpected Outcomes that Affect Animal Well-being [Guide, pp. 28-29] Describe how unexpected outcomes of experimental procedures (e.g., unexpected morbidity or mortality, unanticipated phenotypes in genetically-modified animals) are identified, interpreted, and reported to the IACUC/OB.

The animal care and use program uses several tools to keep the IACUC apprised of unexpected outcomes to animal procedures. The AV is notified via animal health reports, generated by either investigators or animal care staff, when animal concerns are first observed. Investigative staff also contact the AV when they observe significant animal health or welfare issues. The AV and AHT examine the affected animals and make recommendations to the research staff. The AV keeps the IACUC and animal care staff informed of pertinent trends or observations from the health reports.

The IACUC is also notified of unexpected outcomes when investigators fill out the required Annual Update (AU) for their ACUPs. Included in this AU form is a question concerning whether there has been any unanticipated pain, distress or death of animals on study, and what caused these unexpected outcomes.

The IACUC also may be provided additional information regarding unanticipated outcomes by the research staff, AV, AHS, ACS, PAM reports, or direct observation during semiannual inspections.

iii. Physical Restraint [Guide, pp. 29-30]

Note: This section is to include only those protocols that require prolonged restraint. Brief restraint for the purpose of performing routine clinical or experimental procedures need not be described.

1) Briefly describe the policies for the use of physical restraint procedures or devices. Include, if applicable, the IACUC/OB definition of "prolonged."

THE ORD Health IACUC considers prolonged physical restraint to be any time period greater than 15 minutes. Prolonged restraint requires written scientific justification explaining why the restraint is essential for achieving research objectives. Prolonged restraint must be approved by the IACUC. The IACUC requires adequate monitoring of animals during prolonged restraint, though the method of monitoring can range from visual inspections of the animal to continuous review of brain waves from an animal out of view in a closed Farraday cage. The IACUC also requires animals be acclimated to the restraint when possible.

- 2) Describe animal restraint devices that are used or have been used within the last three years. For each device, briefly describe
 - the duration of confinement
 - acclimation procedures
 - monitoring procedures
 - criteria for removing animals that do not adapt or acclimate, and
 - provision of veterinary care for animals with adverse clinical consequences.

Note: If preferred, this information may be provided in a Table or additional Appendix.

Nose Only Exposure tubes: Animals are acclimated to nose-only tubes prior to exposures using a process which gradually increases restraint from 15 minutes on day 1, to 30 minutes on day 2 and 60 minutes on day 3. Most often, proposed exposures would begin on day 4. Exposures range from 1 to 6 hours, 2 to 4 hours being the most common. Animals are monitored visually by research staff at least every 15 minutes.

<u>Electrophysiology studies:</u> Rats are acclimated to restraint in soft plastic tubes (Decapicones) using a 3 day process in which animals are restrained for 5 minutes on day 1, 15 minutes on day 2 and the full restraint, 45-60 minutes on day 3 (day of testing). Animals are generally restrained for approximately 45 minutes. Animals are provided with food rewards following the restraint on days 1 and 2 of acclimation. Animals

are monitored by research staff via continuous observation of brain waves while the animals are enclosed in the test chambers.

Restraint to induce stress: Animals are restrained in the same type of plastic restrainers used for tail cuff blood pressure measurements: an appropriately sized hard plastic tube with a plastic mounting piece which holds the animal in place but allows tail movement. Animals are not acclimated, as the point of this work is to induce stress. Animals are monitored visually by research staff for the duration of the restraint. Animals are not removed from restraint if they fail to acclimate; as stress is the point of the restraint. Restraint is restricted to approximately 15 minutes.

<u>Close confinement to induce stress:</u> Animals are confined in a clear plexiglass container in an open setting. The animal may turn around, but it may not leave the open space. Animals are not acclimated, as the point of this work is to induce stress. Animals are monitored visually by research staff for the duration of the restraint. Animals are not removed from restraint if they fail to acclimate; as stress is the point of the restraint. Confinement may be for up to 3 hours.

<u>Double Chamber Plethysmography:</u> Duration of confinement ranges for different studies, from less than 15 minutes to 2 hours. The mice are acclimated to the tubes for a total of 4 acclimation sessions by placing them into the tubes as follows:

Day 1: 5 minutes/session (am), 15 minutes/session (pm)

Day 2: 30 minutes/session (am), 30 minutes/session (pm),

<u>Criteria for removing animals who do not adapt</u>: During protocol review, the IACUC discusses the information from the researcher regarding how to determine if an animal is not adapting, and the proposed plan for action. Any questions/concerns from the IACUC must be addressed before the document is approved.

Provision of veterinary care for animals with adverse clinical consequences: If there are any animals with adverse clinical consequences, the AV is notified by research staff or animal care staff. The AV examines the animal(s) in question and discusses the exam findings and recommendations with research staff to determine the next step for care.

iv. Multiple Survival Surgical Procedures [Guide, p. 30]

Note: One survival surgical procedure followed by a non-survival procedure is not included in this category.

1) Describe the IACUC/OB's expectations regarding multiple survival surgery (major or minor) on a single animal.

There are no protocols with multiple survival surgery procedures at this time.

Multiple surgical procedures require specific IACUC approval. The ORD Health IACUC requires written justification indicating the rationale for the multiple procedures relative to valid experimental objectives. All multiple surgical procedures would be closely scrutinized by the IACUC and monitored by the Attending Veterinarian and veterinary staff for technique, animal pain and suffering and compliance with the ACUP.

2) Summarize the types of protocols currently approved that involve multiple major survival surgical procedures

Note: If preferred, this information may be provided in a Table or additional Appendix.

The ORD Health IACUC does not currently have any protocols with multiple major survival surgeries.

v. Food and Fluid Regulation [*Guide*, pp. 30-31]. *Note:* This does not include pre-surgical fast.

Summarize the types of protocols that require food and/or fluid regulation or restriction, including:

- justification
- species involved
- length and type of food/fluid regulation
- animal health monitoring procedures and frequency (e.g., body weight, blood urea nitrogen, urine/fecal output, food/fluid consumption)
- methods of ensuring adequate nutrition and hydration during the regulated period

Note: If preferred, this information may be provided in a Table or additional Appendix.

The only species that experience food or fluid restrictions are rats and mice.

Several protocols use glucose tolerance testing (GTT) in rats to study the interactions of air pollution and metabolic syndrome or diabetes. Previous research and human epidemiology indicate there is justification for this

research. The basic procedure for GTT involves fasting for approximately 6 hours prior to collecting a baseline, fasting blood glucose measurement and beginning glucose tolerance testing. Once glucose tolerance testing is over the animals are returned to ad lib feeding.

Food and/or water is not provided to animals during inhalation exposures to environmental contaminants and subsequent pulmonary testing. The point of the food restriction is to ensure that the animals are exposed to the environmental pollutant through inhalation only; this is particularly relevant for environmental contaminants that may react to the food or fluid. Restrictions are generally from 1-6 hours during the day when the animals are less active. These animals are on ad lib food and water prior to periods of fasting during exposure and testing. Animals are weighed and general condition following exposure and testing is reviewed. Animals following exposure and testing are either returned to home cages and ad lib food and water or euthanized and necropsied.

Animals trained by operant conditioning are weight maintained to encourage performance in the operant chambers. The rats are weight-maintained by lowering their daily food supply, but they are not all set to a common weight nor expected to lose weight. Instead, their weight at about 70 days of age is determined (at which point normal growth rate decreases), which becomes their target weight. This can vary across rats, sometimes by greater than 100 g. There is a lower limit for the target weights. Animals are weighed daily during the weekdays and the amount of food to provide is calculated each day. On the weekends animals receive the amount calculated for Friday. Animals are tested and handled daily M-F; their health is evaluated during handling. The animals are also visually monitored daily by animal care staff and any abnormalities such as decreased body condition score, behavioral changes, or decreased activity level would be noted and reported as an Animal Health Report (AHR).

vi. Use of Non-Pharmaceutical-Grade Drugs and Other Substances [Guide, p. 31]

Describe the IACUC/OB's expectations regarding the justification for using non-pharmaceutical-grade drugs or other substances, if applicable.

ACUPs require investigators to list all substances administered to animals over the course of a study. The IACUC requires investigators to state whether or not substances used are pharmaceutical grade. If the substances are available in pharmaceutical grade formulations but the investigators do not plan to use them, they are required to provide the

IACUC with a scientific justification for not using that formulation. These justifications will be weighed and discussed during IACUC review.

Many of the toxins/agents examined at RTPP simply are not manufactured as pharmaceutical compounds or are environmental toxicants which need to be investigated using the toxicants as they would be found in the environment and following their environmental exposure pathways.

vii. Field Investigations [Guide, p. 32]

Describe any additional considerations used by the IACUC/OB when reviewing field investigations of animals (non-domesticated vertebrate species), if applicable.

RTPP currently has no field investigations.

viii. Animal Reuse [Guide, p. 5]

1) Describe institutional policies regarding, and oversight of, animal reuse (i.e., on multiple teaching or research protocols).

RTPP does encourage reduction of animal use and does permit reuse of animals which have experienced procedures which caused only momentary pain or distress. Animals which have experienced more than momentary pain or distress may be reused, but such use is carefully weighed by the IACUC. RTPP allows animals to be transferred from one ACUP to another via a formal Transfer Form. These forms ask for the history of the animals, and specifically ask if any procedures have been performed upon them. All submitted transfer forms are reviewed by the AV. The AV must notify the Director of the ARPO that there are no veterinary concerns with the animals prior to approval of the transfer. If the AV is concerned about the future use of the animals in light of past procedures, the transfer is forwarded to the IACUC for review.

2) Briefly describe the types of activities currently approved that involve the reuse of individual animals.

Note: A list of specific protocols involving reuse of animals should be available during the site visit.

Animals are accepted to the training protocol from other protocols, provided the procedures performed on the animals are minimally invasive, or the animals are naïve.

At this point in time there are a few research protocols which have used transferred mice or rats. The AV has reviewed all transfers, and for most instances only naïve animals were transferred. In one case the IACUC

reviewed the proposed transfer and approved for control and low dose rats (low dose was the No Observed Effect Level) who had been used for motor activity testing (placement in a chamber set up to record movement) to be transferred to a gene expression study for tissue collection.

Animals which have had procedures may be transferred to the Holding Protocol. The Holding Protocol is temporary, not intended for any experimental work, may only be used under defined circumstances, and animals on this protocol are there only while another ACUP is being processed.

3) Describe other instances where the final disposition of animals following study does not involve euthanasia, including adoption, re-homing, rehabilitation, etc.

Note: A list of specific protocols involving reuse of animals should be available during the site visit.

RTPP has applied to the Office of General Counsel of ORD to review an adoption policy but that has not been approved at this time. In lieu of an adoption policy, the IACUC has established a policy that some animals, in particular the USDA covered species and training colony animals, can be retired in place following their years of service to the Agency. These animals will have their basic needs and veterinary care provided until their health degrades and euthanasia is required.

2. Post-Approval Monitoring [*Guide*, pp. 33-34]

a. Describe mechanisms for IACUC/OB review of ongoing studies and periodic proposal/protocol reviews (e.g., annual, biennial, triennial, or other frequency).

While RTPP does not currently accept PHS funds we are PHS assured due to collaborative work with PHS Assured institutions. All ACUPs expire after 3 years and a de novo submission is required which is subject to the same IACUC review as any other new ACUP.

All approved ACUPs and their amendments are subject to annual review. The IACUC requires the PI to fill out an Annual Update (AU) form reporting progress, unexpected adverse effects and similar issues.

The IACUC may also observe procedures, look at records, speak with lab personnel or review other aspects of animal use protocols during the semi-annual facility reviews.

b. Describe the process and frequency with which the IACUC/OB reviews the program of animal care and use.

The ORD Health IACUC meets semiannually to review the RTPP Animal Care and Use Program. All IACUC members and the facility Project Manager are invited to participate in all reviews; a minimum of 2 IACUC members must be in attendance, though generally at least the Chair, AV, a SHEM Representative, and Director of the ARPO attend. The OLAW checklist is used as the basis for this review. The semiannual program review results are reported to, discussed by, and signed by a quorum of the IACUC during the next convened Quarterly business meeting. These IACUC approved reports are then presented to the IO.

(See Appendix 10: IACUC Periodic Report. Facility Inspection and Program Review Reports are included as part of the report to the IO.)

- **c.** Describe the process and frequency with which the IACUC/OB conducts facility and laboratory inspections.
 - Describe the rationale or criteria used for exempting or varying the frequency of reviewing satellite holding facilities and/or animal use areas.
 - If contract facilities or contractor-provided personnel are used, describe procedures used by the IACUC/OB to review such programs and facilities.
 Note: A copy of the last report of these reviews should be included as **Appendix 10**.

The ORD Health IACUC meets semiannually to inspect the animal facilities (including but not limited to facility holding areas, survival surgery areas, satellite facilities, experimental areas, cage wash, and food storage). All IACUC members and the facility Project Manager are invited to participate in all inspections. A minimum of 2 IACUC members review each area. The OLAW checklist is used as the basis for the review. The semiannual facility inspection results are reported to, discussed by, and signed by a quorum of the IACUC during the next convened Quarterly business meeting. These IACUC approved reports are then presented to the IO.

Satellite facilities and animal use areas are reviewed on the same schedule as any other RTPP facility. No contract facilities are in use at the present time.

(See Appendix 10: IACUC Periodic Report. Facility Inspection and Program Review Reports are included as part of the report to the IO.)

d. If applicable, summarize deficiencies noted during external regulatory inspections within the past three years (e.g., funding agencies, government, or other

regulatory agencies) and describe institutional responses to those deficiencies. *Note:* Copies of all such inspection reports (if available) should be available for review by the site visitors.

ORD is not subject to USDA or other government inspection and does not have any inspection reports to present here.

e. Describe any other monitoring mechanisms or procedures used to facilitate ongoing protocol assessment and compliance, if applicable.

RTPP has a formal Post Approval Monitoring program (PAM) where a post approval monitor visits the labs to observe live animal procedures. Observations, answers to questions posed by investigators during the visit, and possible suggestions from PAM visits are delivered to the investigators, the Director of the ARPO, and the IACUC Chair via email after the visit, as well as summarized and reported to the entire IACUC at Quarterly Business Meetings. PAM observations which may involve compliance or welfare issues are brought to the attention of the whole IACUC and handled following the noncompliance procedure.

Research staff and ACS use a system of hang tags to alert all parties to special circumstances which might impact animal welfare. For example, animals which have recently had surgery are marked by a blue hang tag which includes pertinent dates, animals with health reports are marked by red hang tags and so forth. A key for the hang tags is posted in the animal holding rooms.

Appropriate signage for hazards is required to be displayed on suite or holding room doors. Examples range from "Experiment in Process: to "Biohazard", with specific hazards and PPE identified.

PI Feed and Water sheets are used on animal room doors for protocols where the laboratory staff will be doing the feeding/ watering for those animals. These must be checked off daily and emergency contact information available.

Investigating and Reporting Animal Welfare Concerns [Guide, pp. 23-24]
 Describe institutional methods for reporting and investigating animal welfare concerns.

One of the foremost charges of the ORD Health IACUC is to review and investigate concerns involving the care and use of animals at this institution. Animal welfare concerns can be reported in person, by phone or by email to any IACUC member or the IACUC Administrator.

The Ord Health IACUC also maintains a dedicated phone line, monitored Monday - Friday, to receive these reports. Messages may be left anonymously. However,

leaving a name or phone number allows the IACUC to follow up with an individual reporting a concern.

Mechanisms for reporting animal welfare concerns are posted in the animal facility, on the IACUC website, written into the welcome letter sent to every new animal user, and taught during hands-on training.

Once the IACUC receives a report regarding an animal welfare concern, the IACUC follows a standard procedure (the same used for investigating reports of possible noncompliance with approved protocols or regulatory standards). In brief: The incident is brought to the attention of the Chair (or alternate, as appropriate for conflict of interest; reference will only be made to the Chair from here forward) who transmits a summary of the incident to the entire IACUC Committee. The circumstances are investigated to collect information. Investigation is performed by individuals, generally 2, with no conflict of interest. The Chair will discuss the incident with a quorum of the IACUC, and the Committee will decide whether the incident is a valid concern, and if so, if the incident was minor or major. If the incident appears to be of significant consequence, the chair will notify the IO with a preliminary accounting of the incident as soon as possible. Assistance determining major vs. minor may be sought from OLAW. If the incident is deemed to be major, the chair notifies OLAW with a preliminary account of the incident via phone or email. If email is used the IO is copied. The IO and the management of the reported individual(s) will be kept apprised of all developments and correspondence from this point forward. Depending on severity of incident, the IACUC may be required to hold specially convened meetings of a quorum of the IACUC members to decide on remedial actions. Any remedial actions, such as retraining, suspension of animal ordering privileges or protocol suspension, shall be decided with a vote by the committee (majority rules). Once the IACUC has decided upon a suitable course of action, the IACUC prepares a letter to the PI summarizing the incident and the expected corrective and remedial actions. The PI is asked to respond to the IACUC in writing with a plan of action to address the IACUC's concerns and requirements. Once the PI has responded to the IACUC and the IACUC accepts the plan of action, the IO sends a report of the incident, including remedial/corrective actions to OLAW. The Chair and the IO both sign the document sent to OLAW, and copies are sent to the ARPO Director, the IACUC Administrator, AAALAC and USDA if appropriate. The committee may elect to take further action depending on the OLAW response. If OLAW's response is acceptable to the committee, then the incident may be considered officially closed.

If the incident is deemed either not an incident at all or minor and thus not reportable to OLAW, the committee has the following options:

- No further action and closing the incident
- A member of the IACUC informs the reported individuals with verbal or written notification that no further action is needed
- The chair prepares a letter of explanation to the reported individual. The letter should summarize the incident and explain any requested actions.

The management of the reported individual may or may not be copied on the letter.

Regardless of outcome, the person reporting the incident, if known, will also be informed of the outcome of the IACUC's investigations and deliberations.

4. Disaster Planning and Emergency Preparedness [Guide p. 35]

Briefly describe the plan for responding to a disaster potentially impacting the animal care and use program:

- Identify those institutional components and personnel which would participate in the response.
- Briefly describe provisions for addressing animal needs and minimizing impact to animal welfare.

Note: A copy of disaster plan(s) impacting the animal care and use program must be available for review by the site visitors.

The RTP animal care and use program has prepared for a variety of emergencies and disasters ranging from simple power outages through natural disasters to government shutdowns.

Animal Care Staff, Veterinary Staff, and members of the ARPO are essential personnel and always have access to campus, regardless of whether the campus is open or closed for any reason. Classification as essential personnel has been confirmed with campus security and other pertinent administrative personnel.

A lesson learned during the last government shut down resulted in a quorum of the IACUC being declared excepted personnel, allowing them access to campus and EPA resources on call.

Campus security and facilities maintenance are well aware of the presence of research animals on campus, and the needs of the animals during an emergency are considered. The Director of the ARPO works closely with operations and maintenance personnel to ensure that backup power, an independent boiler and similar physical plant essentials are available, and if something does compromise the function of essential operations that the animal care and use program is kept informed and can make any necessary decisions.

The vivarium building is supported by backup generators for electrical power, a backup boiler for heat and steam to operate cage wash, and some water storage capability for both the aquatic program and drinking water for the mammals. Adequate feed and bedding for at least a week is maintained on hand in the facility for all species. Emergency plans address what care and attention the animals receive during an emergency.

The animal care and use program has emergency plans to suit a few different levels of emergency.

A flip book with basic instructions on what to do in case of emergency is centrally located next to the elevator doors throughout the animal facility. This book contains contact information along with clear instructions for what to do during a variety of emergencies including fire, hurricanes and ice storms. Copies of the book are also available for review in the ARPO and the office suite serving the animal care staff.

A separate disaster plan written for animal program management lays out how staffing should be handled during pandemics or natural disasters, what services would be available under those circumstance and what actions would need to be taken to prevent animal pain or suffering.

Since the aquatic facility has markedly different needs than the rodent facility, there is a final operating procedure for what to do during power outages in the aquatic facility. While there is emergency backup power in those rooms, the fish equipment is sensitive and does not always respond exactly as expected. The operating procedure outlines how to keep the aquatic systems as healthy as possible when the unexpected happens.

II. Animal Environment, Housing and Management

Note: Complete each section including, where applicable, procedures performed in farm settings, field studies, aquatic environments, etc.

A. Animal Environment

Note: Facility-specific details regarding mechanical system construction and operation is requested in Section IV.B.5. and **Appendix 11**; current (measured *within the last 12 months*), detailed (by room) performance data must also be provided as indicated in **Appendix 11**.

1. Temperature and Humidity [Guide, pp. 43-45]

a. Describe the methods and frequencies of assessing, monitoring, and documenting that animal room or housing area temperature and humidity is appropriate for each species.

Note: If preferred, this information may be provided in a Table or additional Appendix.

All animal rooms in Building A are monitored by the Building Automation System (BAS) 24/7 by an on-site contractor. Rooms are also equipped with high-low thermometers and hygrometers as secondary measure. The high and low temperatures and current humidity are recorded twice a day, before 9 am and after 2 pm, by the room technician.

Satellite facilities house bees and zebrafish embryos, larvae and juveniles. Bees are housed in special containment caging, and zebrafish are housed in plates or beakers in incubators. Housing for both bees and zebrafish is monitored for temperature and humidity (as appropriate) when animals are present. Monitoring is documented via logs. Life support systems for these species are provided emergency backup power. The IACUC includes reviews of these areas during their semiannual inspections.

No outdoor housing areas are utilized.

See Appendix 11 for HVAC System Summary.

b. List, by species, set-points and daily fluctuations considered acceptable for animal holding room temperature and relative humidity. *Note:* If preferred, this information may be provided in a Table or additional Appendix. [*Guide*, pp. 44 and 139-140]

The Aquatic facility, all zebrafish, is set to 75°F+/- 2°. Humidity is kept around 50%, but that's more for the humans than the fish.

Rodent housing is set to 70° +/- 2, though a few individual rooms are set to 71° or 72°F, to actually maintain that 70°F temp. Relative humidity is maintained at 50%, +/- 10%.

Lagomorph rooms are set to 66°F, +/- 2°. Relative humidity is maintained at 50%, +/- 10%.

Satellite bee facility (in Building B) is set to 25C +/5 and 60% relative humidity.

Satellite zebrafish incubators are set at 26°C +/-2°.

c. Temperature set-points in animal housing rooms and/or environmental conditions are often outside of the species-specific thermoneutral zone. Describe the process for enabling behavioral thermoregulation (e.g., nesting material, shelter, etc.) or other means used to ensure that animals can control their thermoregulatory environment. Include a description of IACUC/OB approved exceptions, if applicable. [Guide, p. 43]

Temperature set points and/or environmental conditions are normally maintained within the thermoneutral zone for the species according to the Guide.

However, the RTPP recognized that there will be both uncertainly about the true value of the species set points (such as the Gordon data on preferred temperatures for mice) and individual variation. To accommodate animal

thermoregulatory needs, most rats and mice are provided with nesting materials and/ or shelters.

There are currently no protocols that require a temperature set point outside the Guide recommendations. There are protocols that by study design require a lack of environmental enrichment. The IACUC requires scientific justification when no environmental enrichment is permitted.

2. Ventilation and Air Quality [Guide, pp. 45-47]

a. Describe the methods and frequencies of assessing, monitoring, and documenting the animal room ventilation rates and pressure gradients (with respect to adjacent areas).

Note: If preferred, this information may be provided in a Table or additional Appendix.

Daily monitoring, assessment and documentation of room ventilation is handled by the automated Building Air System (BAS). Wood, the company contracted to run the operations and maintenance of the EPA RTP campus, has alarms built into the BAS, and the system is monitored by Wood personnel 24/7. An additional personal computer which displays BAS information is set up in the Animal Care Staff office and used to double check temperature, humidity and air flow rates when ACS have questions regarding readings or air pressures up in the animal holding rooms

Satellite facilities are checked by their research labs. Records are available upon request to the IACUC on semiannual facility inspection or if there are concerns.

Independent monitoring, assessment, and documentation of the room ventilation rates and pressure gradients are performed every 3 years. The last performance evaluation was conducted in March-May 2019.

b. Describe ventilation aspects of any special primary enclosures using forced ventilation.

Individual ventilated cage (IVC) rodent racks are in use on a limited basis by the RTPP. RTPP currently uses two types of these systems. Those manufactured by Animal Care Systems, Inc. rely on heat convection and the building's exhaust port to provide "passive" ventilation of the individual cages. These cages have an air exchange rate of approximately 32 cfm. Those manufactured by Tecniplast, Inc. have their own air handling system that can be adjusted for positive or negative flow rates. This system typically operates at 50-70 air changes/hour positive pressure.

c. If any supply air used in a room or primary enclosure is <u>recycled</u>, describe the percent and source of the air and how gaseous and particulate contaminants are removed.

There is no recirculation of air in the Building A animal facility. The air supply is 100% outside air, through 50% atmospheric dust spot efficiency (ASHRAE) pre filters and (DOP) HEPA final filters.

3. Life Support Systems for Aquatic Species [Guide, pp. 84-87]

a. Provide a general description of institutional requirements for enclosures using water as the primary environmental medium for a species (e.g., aquatics).

Institutional requirements for enclosures using water as the primary environmental medium for a species are based on the needs of the species. Currently the only aquatic animal in the RTPP is the zebrafish (Danio rerio). Requirements for these animals are drawn from many sources, including information taken from the online courses on zebrafish offered by the University of Alabama at Birmingham, recommendations from the Zebrafish Husbandry Association, several scientific publications, and operating procedures shared by other institutions.

Water parameter set points are as follows:

pH: 7.4 +/- .2

Conductivity: 1000uS +/- 200uS

Ammonia: 0 ppm Nitrite: 0 ppm Nitrate: <20 ppm

Temperature: 28° +/- 1°
Alkalinity: 75 ppm +/- 25ppm
Hardness: 150 ppm +/- 75 ppm

b. Provide a general description of overall system(s) design, housing densities, and water treatment, maintenance, and quality assurance that are used to ensure species appropriateness.

Note: Facility-specific tank design and parameter monitoring frequencies should be summarized in **Appendix 12** (Aquatic Systems Summary).

There are three types of aquaculture systems in use in the RTPP: Aquaneering stand-alone racks (currently 5 are set up in the aquatics facility; a 6th is in storage), a 5 rack Tecniplast system with a shared water supply, and 2 mini-MEPS (mass embryo production systems) from Aquatic Habitats attached to 2 of the Aquaneering racks. All housing systems use re-circulating water.

Water is first purified via reverse osmosis; there are two RO systems pooling water into shared tanks to ensure a consistent supply. Sea-salt and sodium bicarbonate (pH buffering) are added back to the water via automatic dispensers associated with either the individual Aquaneering racks or the shared Tecniplast technical sump. The mini-MEPS units use the water and filtration from the Aquaneering rack to which they are attached. Currently zebrafish (Danio rerio) are housed on these systems in polycarbonate tanks ranging from 1.8 to 9.5 liters in volume. Water quality parameters are monitored daily and tested weekly, at a minimum, for temperature, pH, ammonia, nitrite, and nitrates. Water hardness and alkalinity are also routinely tested.

The Tecniplast and Aquaneering systems employ a four-stage filtration system (Mechanical, Biological, Finishing, Sterilization/Disinfection) to provide high quality recirculated water. In addition, each system is routinely provided approximately 10-15% fresh makeup water every 24 hours; water exchange rates can be adjusted based on the needs of the individual housing systems. The mini-MEPS use their associated Aquaneering rack for source water and filtration

Fish are housed at a maximum density of approximately 8 adult fish/liter. Assurance is made for adequate individual space per tank to allow for normal movement.

4. Noise and Vibration [Guide, pp. 49-50]

Describe facility design features and other methods used to control, reduce, or prevent excessive noise and vibration in the animal facility.

Rack and tunnel washers are located as far as possible from the animal rooms. The hollow steel doors, filled with sound attenuation material, providing access to these areas are kept closed to minimize noise to the outer hallways. All washing and sterilizing equipment is located on the first floor of Building A and does not pose a noise problem to the adjacent isolation/quarantine area (which houses the only animals on this floor).

The doors to all animal rooms are hollow steel, filled with sound attenuation material, sealed edges, clear, tempered glass windows, self-closing, with automatic drop sills, and are kept closed when not in use. Dirty cages are not dumped either in the animal room or outside adjacent to the animal room. They are transported to the cage washing area where they are dumped. Staff is instructed to be as quiet as possible while in the animal rooms. Staff is also reminded of the need to be as quiet as possible outside of the animal rooms, especially those animal rooms with gestating or lactating animals and rabbits. Rabbits and gestating and/or lactating animals are also housed away from sources of potential noise such as elevators or other heavy equipment.

Fish are housed in holding rooms identical to all other species. The RO water system is being moved from a room that currently holds animals to another room in the Aquatics Facility that does not hold animals to better control noise and vibration for the fish. This move is unlikely to have been completed by the time of the site visit.

B. Animal Housing (all terrestrial, flighted, and aquatic species)

1. Primary Enclosures

Note: A description of primary enclosures used (e.g., cages (conventional, individually-ventilated cage systems (IVCS), etc.), pens, stalls, pastures, aviaries, tanks) should be included in **Appendix 13**.

a. Describe considerations, performance criteria and guiding documents (e.g. *Guide*, *Ag Guide*, ETS 123 and/or other applicable standards) used by the IACUC/OB to verify adequacy of space provided for all research animals, including traditional laboratory animal species, agricultural animals, aquatic species, and wildlife when reviewing biomedical, field and agricultural research studies.

All rodents and lagomorphs are normally housed within the guidelines (predicated upon weight) as set forth in the Guide for the Care and Use of Laboratory Animals (NRC, 2011). Housing for Zebrafish is determined by presiding literature recommendations and Guide recommendations. Alternate housing can be considered by the IACUC (i.e.: metabolism cages, extra large caging to allow for exercise and play).

b. Describe space <u>exceptions</u> to the guiding documents (*Guide*, *Ag Guide*, ETS 123, and/or applicable standards), indicating the references, considerations and performance criteria used (e.g., by the IACUC/OB) to verify adequacy of space provided for all animal species covered by the program. [*Guide*, pp. 55-63]

There is one space exception to the Guide. ACUP# 22-03-003 has an IACUC approved exception for select members of the socialized, male rats in the training colony to stay pair-housed above Guide weight limits. Pair housing helps these rats to remain well-socialized as part of the training program. Caging appropriate for the size of these animals is available, and this is the normal housing for these animals. The investigator has maintained the space exception in the event that all of that caging needs repair or cleaning at the same time. These animals are closely monitored on a daily basis by the ACS and weekly by the AV to ensure continued wellbeing, regardless of the size of the caging.

2. Environmental Enrichment, Social, and Behavioral Management [*Guide*, pp. 52-55; 63-65: *Ag Guide*, Chapter 4]

a. Environmental Enrichment

i. Describe the structural elements of the environment of primary enclosures that may enhance the well-being of animals housed (e.g., resting boards, privacy areas, shelves/perches, swings, hammocks).

All caging is tall enough to allow for normal postural movements as required by the Guide. Polycarbonate/polysulfone/polystyrene cages are clear to allow for animal viewing between cages.

Rabbit cages are constructed and positioned in such a way as to allow viewing of other rabbits within the room. Rabbit racks which allow pair housing for compatible females are also used. Our female rabbits have fought when pair housed, so are now individually housed. The caging allows visual and nose contact.

Rodents are provided with nesting materials unless there is scientific justification to withhold enrichment. Shelters such as igloos, huts, and tubes are also available. Running wheels may also be offered when requested by the PI.

One research experiment uses very large caging (pet rat/ferret cages) to group house rats in order to facilitate enrichment and exercise which are study variables. Rodent density is maintained within Guide floor space requirements. These primary enclosures have two levels, a climbing ladder between levels and running wheels along with other environmental enrichment.

All adult fish are socially housed, and breeding tanks use tulle as enrichment to facilitate breeding behaviors. Embryos and larvae may be singly housed in 96 well (or other) plates, based on study requirements.

Bees are socially and singly housed, depending on the species and the experiment.

ii. Describe nonstructural provisions to encourage animals to exhibit species typical activity patterns (e.g., exercise, gnawing, access to pens, opportunity for exploration, control over environment, foraging, denning, burrowing, nesting materials, toys/manipulanda, browsing, grazing, rooting, climbing).

Based on individual protocols, the following items are available for rodent environmental enrichment: colored-polycarbonate shelter domes, cardboard tunnels, cotton nesting material (Nestlets) or shredded paper nesting material (Enviro-dri), Nylabones, and running wheels. Fruit crunchies (food treats) and sunflower seeds may be scattered through the bedding to encourage foraging and exploration.

Rabbits are provided with assorted toys including plastic suspended keys, or plastic "dumbbells" in addition to varied food supplements such as hay toys, and vegetables. Rabbits are also regularly moved from their primary housing to a larger exercise pen with a rubber mat floor, hay, water bottles, boxes, and greater social contact.

Fish are fed live as well as dry food, though this is as much to encourage growth and reproductive capabilities as it is for enrichment.

Not using environmental enrichment as part of animals housing requires scientific justification in the ACUP.

b. Social Environment [*Guide*, p. 64]

i. Describe institutional expectations or strategies for <u>social housing</u> of animals.

Social housing of social species is the default for the RTPP. Single housing of a social species requires justification on the ACUP and must be approved by the IACUC.

ii. Describe exceptions to these expectations (e.g., veterinary care, social incompatibility) and other typical justification approved by the IACUC/OB for housing animals individually.

The IACUC strongly encourages group housing of social animals. Acceptable reasons for single housing social species may include situations such as: animals in metabolism cages, pregnant females where litters must be identified with the dam, incompatible animals such as rats or mice who fight, male breeder rats or mice, intact adult male rabbits, female rabbits who are aggressive toward other females, or animals on some behavioral studies. Clinical issues may result in single housing; these issues are evaluated on a case-by-case basis by the veterinary staff and discussed with the researcher. Finally, when socially housed animals are euthanized at different time points, remaining animals may be singly housed until the end of a study.

iii. Describe steps taken with isolated or individually housed animals to compensate for the absence of other animals (interaction with humans,

environmental enrichment, etc.).

Individually housed animals must be provided with some type of environmental enrichment such as nesting material, shelters, or items for gnawing to allow for species typical behavior. If these materials cannot be provided to individually housed animals, the investigator must justify the conditions and be approved by the IACUC.

Rabbits are placed into one of two enclosed areas for approximately 120-180 minutes every week. They are singly housed within the individual pens, but the pens are adjacent to each other and both occupied at the same time to allow a degree of socialization. Playpen 1 is 60"X57"X60", playpen 2 is 58"X58"X56". Rabbits in the pens are carefully observed to make sure rabbits are compatible; some rabbits will pull fur from the other rabbit through the fencing. Moreover, rabbits are weighed weekly and groomed (bathing, brushing, and trimming of nails) monthly by the animal care staff allowing for additional human contact.

c. Enrichment, Social and Behavioral Management Program Review [Guide, pp. 58, 69]

Describe how enrichment programs and exceptions to social housing of social species are regularly reviewed to ensure that they are beneficial to animal well-being and consistent with the goals of animal use.

Enrichment is reviewed with each new protocol at regularly convened IACUC meetings. The IACUC currently requires scientific, behavioral or clinical justification when either enrichment or social housing of social species will not be used during a study.

Use of enrichment is reviewed during IACUC facility inspections, post approval monitoring visits, and by the animal and veterinary care staff performing their regular duties.

There is also an IACUC Enrichment Policy.

d. Procedural Habituation and Training of Animals [*Guide*, pp. 64-65] Describe how animals are habituated to routine husbandry or experimental procedures, when possible, to assist animals to better cope with their environment by reducing stress associated with novel procedures or people.

RTPP policy requires that all animals received by RTPP be allowed a minimum period of 3 days (7 days recommended) for acclimation to new housing and husbandry prior to use in research protocols. Acclimation less than 3 days requires justification and approval by the IACUC

Routine husbandry:

All animals are handled as gently and deftly as possible. Care is taken to avoid picking up rodents by base of tail whenever possible. Additional time and care are provided to animals exhibiting nervous or aggressive tendencies. Additional enrichment devices or approved treats may also be made available. Animal care staff are assigned to specific rooms, keeping the animals exposed to a limited number of familiar handlers and care givers to help reduce stress.

Researchers may also take the time to handle the animals, particularly rats and rabbits, prior to any experimental work in order to familiarize themselves with the animals and the animals with them.

Novel procedures:

Nose Only Exposure tubes: Animals are acclimated to nose-only tubes prior to exposures using a process which gradually increases restraint from 15 minutes on day 1, to 30 minutes on day 2 and 60 minutes on day 3. Most often, proposed exposures would begin on day 4. Exposures range from 1 to 6 hours, 2 to 4 hours being the most common. Animals are monitored visually by research staff at least every half hour.

Electrophysiology studies: Rats are acclimated to restraint in soft plastic tubes (Decapicones) using a 3 day process in which animals are restrained for 5 minutes on day 1, 20 minutes on day 2 and the full restraint, 45-60 minutes, on the day 3 (day of testing). Animals are generally restrained for approximately 45 minutes. Animals are monitored by research staff via continuous observation of brain waves while the animals are enclosed in the test chambers.

Water mazes (Morris Water Maze): The tanks used for this test are either a 4' (mice) or 6' (rats) diameter, galvanized, steel tank. Water depth is approximately 15 inches, and the water is maintained at 25C ± 2C to prevent hypothermia. Animals are placed in the water and required to find a submerged platform using visual cues in the room. The animals are observed continuously during the trial by research personnel. Trials last a maximum of 60 seconds. If an animal is experiencing undue difficulty it is immediately removed and allowed to recover. After the trial, the animals are towel dried and placed in a clean cage with dry bedding. The tanks are drained and sanitized at the end of each testing day.

e. Sheltered or Outdoor Housing [Guide, pp. 54-55]

i. Describe the environment (e.g., barn, corral, pasture, field enclosure, flight cage, pond, or island).

There is no sheltered or outdoor housing.

ii. Describe methods used to protect animals from weather extremes, predators, and escape (windbreaks, shelters, shaded areas, areas with forced ventilation, heat radiating structures, access to conditioned spaces, etc.).

Not applicable.

iii. Describe protective or escape mechanisms for submissive animals, how access to food and water is assured, provisions for enrichment, and efforts to group compatible animals.

Not applicable.

f. Naturalistic Environments [Guide, p. 55]

i. Describe types of naturalistic environments (forests, islands) and how animals are monitored for animal well-being (e.g., overall health, protection from predation).

RTPP maintains no naturalistic environments.

ii. Describe how food, water, and shelter are provided.

Not applicable.

iii. Describe how animals are captured.

Not applicable.

C. Animal Facility Management

1. Husbandry

- **a. Food** [*Guide*, pp. 65-67]
 - List type and source of food stuffs.
 - Purina Mills International (PMI) 5001 (pelleted and meal) –rats
 - PMI 5008 -gestating and nursing rats, and pups
 - PMI 5002 (certified PMI 5001) –rats
 - PMI 5015 mice
 - PMI Prolab RMH 3000 mice PMI Prolab Hi Fiber Rabbit Chowrabbits
 - Oxbow Hay Stacks and Hay Toys
 - Oxbow Critical Care formula- rabbits

- Harlan Teklad NIH 07 –rats
- Assorted vegetables -rabbits (as directed by Attending Veterinarian)
- Oxbow (Timothy and other hay and legume hay) –rabbits
- Research Diets precision synthetic pellets rats
- Bio Serv precision synthetic and grain-based pellets rats
- Bio-Serv specialty gel feeds- rodent and rabbit, as needed
- Brine Shrimp Direct (brine shrimp cultured on-site) fish
- Rotifers- fish
- Zeigler NTP 2000 –rats
- Skretting Gemma Micro Diet -fish
- Lab Diet PMI 5P00 mice
- Fresh, frozen honey bee-collected corbicular pollen Brushy Mountain Bee Farm (Moravian Falls, NC) or other vendor.
- Sterilized honey bee-collected corbicular pollen from Stakich (Bloomfield Hills, MI) or other vendor.
- **ii.** Describe feed storage facilities, noting temperature, relative humidity, and vermin control measures, and container (e.g., bag) handling practices, for each of the following:
 - vendors (if more than one source, describe each)
 - centralized or bulk food storage facilities if applicable
 - animal facility or vivarium feed storage rooms
 - storage containers within animal holding rooms

All PMI chows except PMI 5001 are received from Granville Milling Co. where it is stored in a vermin-proof, air-conditioned building. PMI 5001 chow is received from Barnes Supply Co. whose storage facilities are also vermin-proof and air-conditioned.

Once feed is delivered to the RTPP, it is stored in a "cold room" maintained at 35-45°F on the first floor of the animal facility. Feed is kept on racks or pallets at least 6 inches above the floor and 6 inches away from the walls, and stock is rotated such that the oldest supplies are used first. Vermin control measures take place outside the cold room, with live traps located next to the entry airlocks to the facility.

Milled rodent and rabbit chows are removed from their original packaging (bags), placed into heavy duty plastic bags contained in 30-gallon plastic barrels on dollies. When not in use the bags are twisted closed and the barrel closed with a lid. Each barrel is labeled as to the feed type and the milling date of the feed contained in the barrel. Specialty chows (Bio Serv, Research Diets, Zeigler, etc.) are maintained in smaller, quantity

appropriate containers or packaging with the feed type and milling and/or expiration dates noted on the container.

Fresh vegetables are maintained in the cold room and provided fresh daily to the rabbits. Reserves of Oxbow hay are maintained in the cold room; sufficient hay for a week is brought up to the rabbit rooms at the start of the work week.

Bee food is stored in a refrigerator in the bee lab.

Fish food may be frozen or stored in the cold room. Live food is grown in an incubator in A280 A. Rotifers are maintained by the research lab, as needed for larvae and juvenile fish.

iii. Describe special food preparation areas, such as feedmills and locations where special diets are formulated, if applicable. Include in the description sanitation and personnel safety practices (noting that respiratory protection is described in Section 2.I.A.2.b. ii. Standard Working Conditions and Baseline Precautions above).

There are no food preparation areas for mammalian species as part of the RTPP. Artemia for fish are cultured in a specially designed cabinet located in A280-A. Rotifers are maintained by the research lab, as needed for larvae and juvenile fish.

There are some specialty diets commercially milled for specific research projects, such as a powdered feed produced for bioavailability studies of lead or arsenic from brownfield or Superfund site soils. Procurement and handling of these diets are done by the investigative staff, not husbandry staff with the exception of some technical service requests to swap out preprepared feeders of these specialized diets. Animal care and investigative staff meet and discuss all precautions necessary to handle these food hoppers. This feed is considered a test article, and responsibility for the preparation and disposal of the feed belongs to investigative staff.

iv. Describe how food is provided to various species (*ad libitum*, limited amounts, types of feeders).

Rodent chow is provided in interior slotted V-type, U-type feeders, or wire lids. Rabbit chow is provided in exterior J-type feeders. Powdered chow is provided in screened feeders designed for this application or in small stainless-steel bowls. All chow is provided ad libitum except for the following:

Older rabbits are fed approximately 6 oz. daily to avoid obesity problems associated with caged NZ white rabbits

Protocol-specified weight-maintained rats (weights are maintained at an individual target weight for each, determined as part of the study) are fed once daily a calculated amount of feed.

Fish are provided dry food 2 times per day then fresh food, artemia, 2 times per day on weekdays to maintain egg production. Fish are provided dry and fresh food once a day on weekends to maintain homeostasis. Eggs produced on weekends or holidays are usually eaten by the fish, providing additional calories.

Bees are provided food by the investigator twice a week, based on his operating procedure.

v. Describe special food quality control procedures including procedures for rotating stock, monitoring milling dates, nutritional quality, bio load, chemical contaminants, etc.

Each commonly used food type is analyzed a minimum of two times per year for antibiotic residues, trace minerals, pesticides, microbial activity and PCBs. The analysis is performed by an off-site laboratory (Sani Pure Food Laboratories).

Rodent and rabbit chow is ordered and delivered on a biweekly basis from local vendors. Typically, enough feed to last two weeks, plus 25%, is ordered. Feed inventory and milling dates are checked with each new delivery to assure stock rotation. Any feed remaining from the previous week is marked to ensure use before newer stock.

Fish foods, special order chows, and precision pelleted foods are ordered on an as needed basis. Expiration dates are monitored to ensure proper nutritional value.

b. Drinking Water [Guide, pp. 67-68]

i. Describe the water source, treatment or purification process, and how it is provided to the animals (e.g., bowls, bottles with sipper tubes, automatic watering, troughs, ponds, streams).

Chlorinated water is provided the vivarium by the Durham City Water System. Animals are provided access to water by the automatic watering system (Edstrom) or by bottles equipped with stoppers and sipper tubes. Drinking water entering Building A is first filtered via a 5-micron sediment filter and then via an activated charcoal filter prior to being re-chlorinated (1-2 ppm) and stored in a 200 gallon water storage tank. Water from this tank is then pumped to all animal holding rooms through stainless steel header lines as part of an automatic watering system. As the water enters the animal holding room, it passes through pressure reducing stations at each suite where the pressure is reduced from 40-60 psi down to 3-5 psi. The pressure reducing stations also contain devices to detect problems with pressure and flow. Automatic high pressure flushing of all distribution piping and rack manifolds is performed every 12 hours.

Water bottles are filled at a water bottle filling station using the same water supply as the automatic watering system.

ii. Describe methods of quality control, including monitoring for contaminants.

The water supply is analyzed twice a year by an off-site laboratory (National Testing Laboratories). Samples are collected from various points including incoming supply, water bottle fill stations, and pressure reducing stations, and are screened for trace minerals, pesticides, microbial activity, PCBs, fluoride, trihalomethanes, pH and hardness.

iii. If automatic water delivery systems are used, describe how they are maintained and sanitized.

Automatic high pressure flushing of all distribution piping and rack manifolds is performed every 12 hours in Building A. Animal racks are checked monthly for the presence of pseudomonas. If pseudomonas is found water is taken from the room supply line and tested. If this water tests positive the entire suite automatic watering system is sanitized using a portable sanitizer (Edstrom Industries). This process involves introducing hyperchlorinated water into the water lines, allowing it to sit, and then flushing it from the system.

c. Bedding and Nesting Materials [*Guide*, pp. 68-69]

i. Describe type(s) and how used for various species.

Direct Bedding (rodents)

- Alpha-dri, Shepherd Specialty Paper, virgin cellulose paper
- Pine Shavings, Northeastern Products Corp., heat-treated
- Beta Chips, Northeastern Products Corp., heat-treated

Indirect Bedding

Alfa Cob, rabbit cage pans

Animal Cage Board, Ancare, rodent

Rodent nesting materials include Nestlets and Enviro-dri.

Bedding and nesting materials are selected by the Principal Investigator when ordering animals.

 Describe bulk bedding storage facilities, if applicable, including vermin control measures.

Not applicable.

iii. Describe quality control procedures, including monitoring for contaminants.

Direct animal bedding is analyzed twice a year by an off-site laboratory for trace minerals, pesticides, microbial activity, and PCBs.

d. Miscellaneous Animal Care and Use Equipment

i. Describe motorized vehicles and other equipment (e.g., trailers) used for transporting animals, noting the type and how the cargo compartment is environmentally controlled, if applicable.

Animals are transported between facilities via a Dodge van specially modified for animal transport. The van has dual heating and air conditioning for climate control and interior fans for enhanced air movement and circulation. An electric hi-lo thermometer is kept in the van at all times to monitor the interior temperature. A separate flatbed truck is used for waste removal.

ii. Describe other animal care related equipment used in the animal care program (specialized equipment for exercise or enrichment, high pressure sprayers, vacuum cleaners, tractors, trailers, spreaders, etc.).

The facility has wet-dry electric vacuum cleaners, floor buffers, and a portable sanitizer. Cage changing tables (100 cfm clean benches) and dump stations (NuAire) are also available for use if necessary.

e. Sanitation [Guide, pp. 69-73]

i. Bedding/Substrate Change

1) Describe frequency of contact and non-contact bedding change for each species and enclosure type (solid-bottom or suspended) or pen.

Conventional, solid-bottom rodent cages are typically changed, at a minimum, twice a week for animals which are group housed. Animals which are housed singly are typically changed once a week. Females with litters are typically not changed until PND 7 for mice and PND 5 for rats. IVC rodent cages are typically changed once a week for group housed animals and every other week for individually housed animals. Factors which may affect cage change frequency include: bedding type, species of animal, size of animal, sex of animals, compatibility, size and type of caging, and experimental considerations. Suspended rabbit cages are changed once a week, with the fecal pans being changed twice a week. The new large pen rat cages are changed once a week, though this frequency may be increased once the cages have been in use for a few months.

2) Describe any IACUC/OB approved <u>exceptions</u> to frequencies recommended in the *Guide* or applicable regulations and the criteria used to justify those exceptions.

No exceptions are currently approved.

3) Note the location where soiled bedding is removed from the cages/enclosures and where clean bedding is placed into the cages/enclosures.

Soiled bedding is collected in the return "dirty" wash areas (A197 dirty side). Clean bedding is placed into cages in "clean" wash areas (A197 clean side)

- ii. Cleaning and Disinfection of the Micro- and Macro-Environments Note: A description of the washing/sanitizing frequency, methods, and equipment used should be included in Appendix 14 (Cleaning and Disinfection of the Micro- and Macro-Environment) and Appendix 15 (Facilities and Equipment for Sanitizing Materials).
 - **1)** Describe any IACUC/OB approved <u>exceptions</u> to the *Guide* (or applicable regulations) recommended sanitation intervals.

No exceptions are currently approved.

- **2)** Assessing the Effectiveness of Sanitation and Mechanical Washer Function
 - **a)** Describe how the effectiveness of sanitation procedures is monitored (e.g., water temperature monitoring, microbiological monitoring, visual inspections).

Hot water sump temperatures for mechanical washers are noted twice daily and recorded. Cages are rewashed, if, after exiting the tunnel washer, any fecal material or foreign matter remains. RODAC plates and CHARM Pocket Swab Plus™ ATP detection swabs are used daily as quality control tests.

b) Describe preventive maintenance programs for mechanical washers.

All mechanical washers are checked each morning for water and steam leaks, nozzle and pipe obstructions, and to ensure clean debris strainers. The water temperatures are also checked and recorded (am and pm) to ensure proper operating temperatures. If any problems are noted they are corrected before washing may proceed.

An on-site engineering contractor, with expertise in cage and rack washer maintenance (Wood), also routinely checks the machines (typically weekly but not less than monthly).

f. Conventional Waste Disposal [Guide, pp. 73-74]

Describe the handling, storage, method and frequency of disposal, and final disposal location for each of the following:

i. Soiled bedding and refuse.

Soiled bedding and refuse are bagged, secured, and transported to the incinerator which is located in the Central Utility Plant, Building 106 on the NIEHS Campus at 111 T.W. Alexander Drive for burning twice daily, Monday through Thursday. Miscellaneous non-animal, non-toxic refuse is taken to designated dumpsters for landfill disposal on an as needed basis.

ii. Animal carcasses.

Animal carcasses are bagged, secured, and stored in a designated freezer located in A197-A to await boxing for delivery to the incinerator (Central Utility Plant, Building 106, NIEHS Campus) for burning. Animal carcasses reserved for post- mortem evaluation are bagged, identified by investigator,

and stored in designated refrigerators located in A198, A280, A390, A490, and A587.

Bees are stored temporarily in a freezer in the bee lab, and ultimately autoclaved before being incinerated as part of non-regulated laboratory waste.

g. Pest Control [Guide, p. 74]

- i. Describe the program for monitoring and controlling pests (insects, rodents, predators, etc.). Include a description of:
 - monitoring devices and the frequency with which devices are checked
 - control agent(s) used and where applied, and
 - who oversees the program, monitors devices, and/or applies the agent(s).

The program employs rigorous sanitation procedures and physical means to control vermin utilizing the following:

- humane, live capture traps in hallways/storage areas/entry areas
- roach "motels" and ant traps in breakrooms or locker rooms (if indicated)
- daily sanitation of facilities using approved disinfectants, with special attention to locker areas.
- **ii.** Describe the use of natural predators (e.g., barn cats) or guard animals (e.g., dogs, donkeys) used for pest and predator control, if applicable.

No such natural predators are used.

iii. Note how animal users are informed of pesticide use and how animal users may opt out of such use in specific areas.

No application of chemical pesticides is performed in the animal facilities.

h. Weekend and Holiday Animal Care [Guide, pp. 74-75]

i. Describe procedures for providing weekend and holiday care. Indicate who (regular animal care staff, students, part-time staff, etc.) provides and oversees care and what procedures are performed.

Coverage for weekends and holidays is provided by typically two animal technicians. All mammalian rooms are checked daily for deaths, illness, wet cages, low feed/water, automatic watering function and proper room

temperature/humidity. Fish are fed and any necessary water quality checks are performed. A weekend health report sheet is posted on Fridays. Qualified technical staff perform experimental duties, e.g., animal dosing, based on their technical abilities, as requested by research personnel and after approval by the ARPO.

ii. Indicate qualifications of weekend/holiday staff if not regular staff.

Weekend and holiday workers are regular staff.

iii. Describe procedures for contacting responsible animal care and/or veterinary personnel in case of an emergency.

Lists of home, work and cell phone numbers of pertinent Animal Resources Program Office staff, the animal care contract Project Manager, and the Attending Veterinarian are posted on primary entrance doors throughout the animal facilities. A call list is also maintained at the EPA Guard Desk which is manned 24 hours a day. This list not only contains the numbers of responsible animal care personnel, but also contains the names of maintenance people as well (e.g., plumbers, HVAC, etc.) in the event of an equipment alarm or a problem noted during security rounds.

Emergency contact information for animal users (PI's, research staff) is also posted inside animal suites on associated holding room doors. Emergency contact information is also posted on the bee lab door.

2. Population Management [*Guide*, pp. 75-77]

a. Identification

Describe animal identification methods for each species (e.g., microchips, cage/tank cards, collars, leg bands, tattoo, ear tags, brands).

All rodents/lagomorphs are identified with a cage card providing the following information:

- Species/Strain
- Sex
- Date of birth (if provided)
- Date received
- Investigator's name and office phone number
- Number of animals per cage
- Source
- Animal Care and Use Protocol Number

Lagomorphs also have a name recorded on the cage card and the animal's individual medical record. Animal's ears may be marked with ink during playtime.

Many experimental animals, particularly chronic and inhalation studies, are identified by an ear punch code, numbered tag, tail marking or transponder, depending on the investigator's protocol requirements.

Individual fish tanks are identified with labels indicating the tank number, date of birth, fish strain, ACUP #, Investigator name and office phone number. Individual fish racks are similarly identified with laminated cards which include at a minimum:

- Species/Strain
- Investigator's name and office phone number
- Source
- ACUP#

Bees are not individually identified.

b. Breeding, Genetics, and Nomenclature

i. Describe the program for advising investigators on the selection of animals based on genetic characteristics.

Any questions regarding these subjects are addressed either when the particular ACUP is reviewed or when an investigator contacts the Attending Veterinarian.

ii. Describe the program for advising investigators on using standardized nomenclature to ensure proper reporting of the identification of the research animals with regard to both the strain and substrain or the genetic background of all animals used in a study.

Any questions regarding these subjects are addressed either when the particular ACUP is reviewed or when an investigator contacts the Attending Veterinarian.

During protocol review, the AV requests standard nomenclature on all research animals.

iii. Describe genetic management techniques used to assess and maintain genetic variability and authenticity of breeding colonies, including recordkeeping practices (*Guide*, pp. 75-76).

Currently there are no breeding colonies at RTPP aside from the zebrafish, which are an outbred colony. Milt from this colony is cryopreserved. Fish from the original source (ZIRC) are re-introduced into the colony on a periodic basis handled by the AV and the investigative staff in charge of the colony.

General guidelines for maintaining rodent breeding colonies are in the ORD-RTP-Health IACUC Policy: *Guidance and Requirements for a Mouse Breeding Colony in ORD-RTP EPA/RTP Campus*, available from the IACUC and on the IACUC website. Investigators planning on establishing a breeding colony also take the AALAS Learning Library courses on breeding colonies. The IACUC in RTP requires a colony management plan be submitted along with the animal care and use protocol. The colony management plan will address:

- Criteria for Selection of Breeders
- Identification Method
- · Breeding Method
- Population Management
- Colony Oversight
- Genotyping
- Record Keeping

The colony management plan is reviewed alongside the protocol, and colony management records are subject to review by the IACUC, AV, and PAM.

iv. For newly generated genotypes, describe how animals are monitored to detect phenotypes that may negatively impact health and well-being. Note that the methods used to report unexpected phenotypes to the IACUC/OB should be described in section 2.1.B.1.c.ii, "Unexpected Outcomes that Affect Animal Well-Being."

Any questions regarding these subjects are addressed either when the particular ACUP is reviewed or when an investigator contacts the Attending Veterinarian. There are currently no newly generated genotypes, nor active protocols to create new genotypes.

III. Veterinary Care [Guide, pp. 105-132]

Note: Complete each section, including, where applicable, procedures performed in farm settings, field studies, aquatic environments, etc.

A. Animal Procurement and Transportation [*Guide*, pp. 106-109; *Ag Guide*, pp. 8; 45; 50-57]

1. Animal Procurement

Describe the method for evaluating the quality of animals supplied to the institution (from commercial vendors, other institutions, etc.).

Commercial Vendors:

Animals purchased from commercial vendors are must meet the EPA Bioexclusion List. Health reports are reviewed by the AV. Upon arrival, animals are checked by ACS and the accompanying report is reviewed by ACS to be sure no health report information has changed. Every 6 months, for 1 – 2 weeks, shipments of animals from most commonly used source rooms are selected for testing on arrival. Feces and fur swabs are taken as animals are placed into new cages. These are sent for PCR testing at IDEXX Bioresearch to ensure that the health report from the vendor is correct. PIs are informed that the testing will take place, but as it is non-invasive and no procedures are done to the animals except fur swab, the process does not delay the acclimation period. This replaces the previous vendor surveillance program where animals were ordered from commonly used source rooms, euthanized and tested on arrival. This change was instituted to reduce the number of animals used each year while still maintaining the integrity of the program.

Other Institutions:

The Attending Veterinarian requires and subsequently reviews 6-12 months of animal colony health data from the proposed provider institution. No animals are allowed entry into the EPA animal facilities that do not meet the EPA Bioexclusion List. If sufficient test results are unavailable, the provider institution must make arrangements to have these tests performed. Proof of health status is mandatory before authorization to ship (receive) is granted by EPA.

2. Transportation of Animals

Describe how animals are transported between outside sources and the institution and within the institution, including loading, unloading, level of biosecurity, immune status and specific pathogen status (consider all species, including aquatic and semi-aquatic species).

Outside Sources:

All outside source animals (rats, mice, fish and bees) are from commercial vendors delivered via climate-controlled vehicles. In the event animals were to be picked up or delivered locally it would be done using the contractor-provided climate-controlled animal transport van (except bees, which are not relocated after arrival at EPA). All animals received or transported in this manner would be properly identified and securely housed in either approved shipping crates or in cages fitted with wire and micro isolator tops.

Rats and Mice:

Upon arrival from a vendor, the animal shipping crates are unloaded from the delivery truck into the clean loading dock (#11). After movement to the adjacent

receiving area they are wiped down with an approved disinfectant. After being wiped down, all crates are sorted by Principal Investigator name. The animal care staff counts the total number of boxes and notes if any appear to have been crushed or damaged during transport. Any boxes which appear to have been damaged (crushed, ripped, wet) are noted on the receipt papers. The attached vendor health certificates are then carefully scrutinized and compared to the EPA Bioexclusion List. If any organisms are noted that are on the Bioexclusion List the boxes from this vendor/production area are set aside and are not opened. The Project Manager is immediately notified who in turn immediately notifies the Attending Veterinarian. The Attending Veterinarian issues instructions on how to proceed.

From the receiving area the animal crates are transported to the preassigned animal room for housing. Once the crates are within the housing room they are opened. Each animal is removed, sexed, carefully checked for overall vitality, housed, and provided fresh food and water. Problems such as dead, sick, injured, or heat stressed animals are noted and are brought to the immediate attention of the Project Manager's office and the Attending Veterinarian. Newly arrived animals are observed closely several times daily during the first week in the facility.

Fish:

Fish and fish embryos from approved vendors with approved health status are shipped next day delivery in foam coolers. On arrival they are wiped down with an approved disinfectant and immediately taken to the fish suite (A280). Fish are acclimated to tank temperature by floating the primary shipping enclosures in the tanks prior to releasing the fish into the new housing. Fish embryos are received in a like manner; however, they are not housed in the animal facility but are instead taken to the Pl's lab where they are reared to 2-4 weeks of age before being moved to the animal facility. Note: Adult fish have not been received in years. If this practice started up again, animals would be quarantined on a dedicated rack and not simply introduced into the general population.

Bees: Arrive from vendor via commercial shipper.

Within Institution Transport:

Rodents are periodically transported between campus facilities. Rodents may be transported from the A vivarium to High Bay and from High Bay to Building B using the contractor-provided animal transport van. Arrangements are made between facilities prior to transport to ensure staff will meet the transport van and that adequate housing is ready and waiting for the animals upon their arrival. The temperature of the animal transport van is checked, and once satisfactory the cages of animals are carefully placed in the cargo hold of the van in such a manner as to prevent movement during transport. Animals are transported in vendor shipping crates or cages fitted with wire and micro isolator tops. Once the animals are received at High Bay they are immediately taken to their destination

area, removed, sexed, checked for overall vitality, housed, and provided fresh food and water. Study animals destined for B wing will be necropsied upon arrival by research staff.

Transport to Other Institutions:

Animals may be shipped from EPA to another facility with the expressed consent of the receiving institution. Travel arrangements must be made in advance using either the contractor-provided climate-controlled animal transport van or an approved commercial shipper and the assurance that staff and housing will be available for the animals when they arrive at the receiving institution.

B. Preventive Medicine

- 1. Animal Biosecurity [Guide, pp. 109-110]
 - **a.** Describe methods used to monitor for known or unknown infectious agents. Note that if sentinel animals are used, specific information regarding that program is to be provided below.
 - The RTPP animal care and use program utilizes the RTPP Sentinel Animal Testing Program for all mammalian species. Species-specific sentinel animals are used to monitor the health of the animal population. For rodent species, sentinels are placed in each room and exposed to feces and dirty bedding from all cages within the specific room. The sentinels are then submitted for serological, microbiological and histopathological evaluations on a predetermined program basis.
 - Health monitoring of non-mammalian species (fish-Danio rerio) is performed by either periodic testing of experimental animals that are culled from the population every 3 months and by testing animals observed to be sick. Testing includes microscopic analysis and histopathology.
 - **b.** Describe methods used to control, contain, or eliminate infectious agents.

Any animal found ill by the animal care staff or research staff is reported via a written Animal Health Report (AHR). The animal care contract office assigns a sequential AHR number, and the specific cage is marked using a red plastic hang-tag with the AHR number and the date of the report

The Attending Veterinarian (AV), Animal Health Technician (AHT), and pertinent investigators are immediately informed via e-mail and/or telephone by the animal care contractor's office. The Animal Resources Program Office (ARPO) will also be informed. Unless immediate euthanasia is requested by

the investigator, the AHT and/or AV will perform a physical examination and discuss the findings with the investigator.

The veterinary staff will initial the red AHR hand-tag. Appropriate course of action is determined upon discussion with the research staff and VT and/or AV and emailed. Clinical treatment regimens are ordered and monitored regularly by the veterinary staff. An individual animal health report record and animal treatment sheet (if applicable) are maintained in the animal holding suite until the case is closed by a member of the veterinary staff. Closed records are maintained by the AV and ARPO.

If an animal or animal population is determined to be infected with a pathogen that may pose a risk to surrounding populations, and the individual or population is not culled, a graduated isolation/quarantine protocol is established. Depending on the pathogen and the adjacent populations, the room may be quarantined with restricted personnel and animal movement. Routine cage changing and room cleaning would be performed by designated animal care staff last. Personnel performing husbandry, etc., would be prohibited from further entry into other animal areas. If the population posed an eminent risk, the entire population would be removed to the High Hazard suite or isolation/quarantine area of Building A or euthanized depending on the severity of the risk.

2. Quarantine and Stabilization [*Guide*, pp. 110-111]

a. Describe the initial animal evaluation procedures for each species.

Rodents and Lagomorphs:

Upon arrival, the animal shipping crates are unloaded from the delivery truck and are wiped down with an approved disinfectant before being sorted according to PI name.

The interior temperatures of randomly selected crates are taken and recorded. If the interior crate temperature is lower than $60 \square F$ or higher than $80 \square F$ the Attending Veterinarian is contacted. The Attending Veterinarian issues instructions on how to proceed.

Animal Care Staff count the total number of boxes and notes on the shipping receipt if any appear to have been crushed, damaged or wet during transport. The attached vendor health certificates are then carefully scrutinized and compared to the EPA Bioexclusion List. If any organisms are noted that are on the Bioexclusion List the boxes from this vendor/production area are set aside and are not opened. The Project Manager is immediately notified who in turn immediately notifies the Attending Veterinarian. The Attending Veterinarian issues instructions on how to proceed.

From the receiving area the animal crates are transported to the preassigned animal room for housing. Once the crates are within the housing room they are opened. Each animal is carefully observed for abnormalities and sexed before being caged. Any problems such as dead, sick, injured, or heat stressed animals are noted and are brought to the immediate attention of the Project Manager's office and the Attending Veterinarian. Newly arrived animals are observed closely several times daily during the first week in the facility.

Fish: Adult fish have not been delivered to the RTPP in many years. Occasional shipments of bleached embryos have been delivered from ZIRC. These fish may be used for experiments immediately or may occasionally be raised to be adults and incorporated into the breeding colony for an infusion of new genes. In either case, the embryos are brought to the lab, not the Building A aquatic facility. Fry may eventually be brought to the aquatic facility and placed on a quarantine rack until health is assured.

Bees are signed for by either animal care staff or chemical services personnel at the loading dock. The researchers are called immediately upon delivery, the animals promptly picked up, and the animals transported to the bee laboratory in B Building. Bees do not enter the A Building Vivarium.

b. Describe quarantine facilities and procedures for each species. For each species, indicate whether these practices are used for purpose-bred animals, random-source animals, or both.

Purpose Bred:

Rodents received from sources other than the commercial vendors normally utilized (e.g., universities, private research institutions) are required to be free of adventitious pathogens as listed in the current EPA Bioexclusion List. Upon receipt, these animals are subject to a quarantine period for verification of health status prior to entry into the general animal population. Quarantine housing is established in A196. Health status verification by serology, parasitology, and histology is performed on cohort animals or sentinel animals. Animals would be tested by non-invasive PCR sampling on arrival and started on anti-parasiticides via feed. Animals would be held for a period of time negotiated based on health reports available, then released into general population if clean of infectious pathogens on the bioexclusion list.

Fish arriving from a non-approved vendor go either into the quarantine rack if it is empty of other fish, or into static tanks in the aquatic quarantine room.

Random-source Animals:

RTPP does not use random source animals.

Building A has specific housing areas for the quarantine/isolation of specific animal populations should the need arise. Suite A196 is designated as a quarantine area, contains six cubicles and is located on the first floor away from all other animals. The pressure differential in each animal cubicle can be individually set to either positive or negative pressure as needed, and the suite is equipped with a Class II-Type B2 Biological safety cabinet. Animal Care Systems IVC racks are utilized when quarantined animals are housed in A196, These racks are connected directly to building supply exhaust ports.

Specific quarantine operational procedures apply to quarantine areas, including PCR testing on the new population, treating with anti-parasiticides and waiting for test results before allowing animals to go into general housing. Routine cage changing and room cleaning would be performed by designated animal care staff last. Personnel performing husbandry, etc., would be prohibited from further entry into other animal areas.

c. Describe the required/recommended stabilization period for each species.

Investigators are required to allow all newly arrived mammals a minimum of 3 days to acclimate before undergoing experimental manipulation. The recommended acclimation period is 7 days. Acclimation periods shorter than 3 days require scientific justification and IACUC approval.

3. Separation by Health Status and Species [Guide, pp. 111-112]

a. Describe the program for the separation of animals by species, source, and health status. If the animals in different status are not maintained separately, describe circumstances in which mixing occurs and explain the rationale for mixing.

RTPP does not house different species of animals in the same holding room.

RTPP does not maintain animals from different sources in separate rooms. All animals accepted into the facility have met the EPA Bioexclusion List, therefore all animals are of the same health status.

b. Describe situations where multiple species may be housed in the same room, area, or enclosure.

Multiple species are not housed in the same room.

c. Describe isolation procedures and related facilities for animals.

Isolation of individual animals is not a routine procedure. Animals which are found to be in ill health remain on the rack and in the room in which they are being housed. Animals in ill health are usually sick from non-communicable issues such as malocclusion or fighting wounds. Quarantining animals under these circumstances is not required. Depending on the situation they may be singly housed (within the room).

Should it be determined the animal does pose a significant health risk to the other animals in the room or suite it would be moved to a designated quarantine/isolation area or euthanized upon the recommendation of the Attending Veterinarian.

C. Clinical Care and Management [*Guide*, pp. 112-115]

- 1. Surveillance, Diagnosis, Treatment and Control of Disease [Guide, pp. 112-113]
 - **a.** Describe the procedure(s) for daily observation of animals for illness or abnormal behavior, including:
 - the observers' training for this responsibility
 - method(s) for reporting observations (written or verbal)
 - method(s) for ensuring that reported cases are appropriately managed in a timely manner.

All animals are observed a minimum of twice daily M-F and once daily on weekends and holidays by animal technicians for signs of illness. If any problems are observed, an Animal Health Report (AHR) is generated by the reporting technician. During normal working hours the technician promptly delivers the AHR to the Project Manager's office. Notice of AHR is sent via email to the Principal Investigator (PI), Attending Veterinarian (AV), and Animal Health Technician (AHT). In the event of a serious health problem the AV is immediately contacted by phone. The AHT then personally examines the animal and consults with the AV regarding the course of action. Outside normal working hours the AV is contacted by phone. Depending on the case and the history of that group of animals, AV may come on site and check the animal(s).

Animals with active AHRs requiring treatment are observed once or twice daily M-F by the AHT. Animals not receiving active treatments, or not considered critical cases, are observed 1-2 times per week by the Veterinary staff.

Animal care personnel have been trained in disease recognition by a manager, supervisor, or AV using AALAS or other in-house training materials. On many occasions the ACS are the first to observe a problem.

b. Describe methods of communication between the animal care staff and veterinary staff and the researcher(s) regarding ill animals.

Animal room technicians report animal health problems by filling out an Animal Health Report (AHR) form. The animal care staff assigns a sequential AHR number, and the specific cage is marked using a red, plastic hang-tag with the AHR number and the date of the report

The Principal Investigator (PI), AV and AHT are notified by e-mail regarding the condition of the animal. If the condition is severe the AV is immediately contacted by phone, and the PI notified by phone and email. The veterinary staff will perform a physical examination of the animal and mark the red hangtag with their initials and date of the exam. The clinical findings and recommendations are summarized on an AHR which is maintained in the animal's suite as long as the case remains open. The AV and/or AHT determine an appropriate course of action and discuss plans with the research staff. Any treatments are recorded on an Animal Treatment sheet which is maintained with the Animal Health Report record.

If the research staff is not available, the AV will determine the appropriate course of action.

c. Describe the preventive medicine and health management/monitoring programs (e.g., physical examination, TB testing, vaccination, hoof/nail trimming, teeth cleaning/floating, vendor surveillance, use of sentinel animals) for each species.

Sentinel Animal Program

Rats and Mice: The program utilizes a sentinel animal program for rodent species. Same species sentinel animals are used to monitor the health of the animal population. For rodent species, sentinels are placed in each room and exposed for a minimum of 2 weeks to feces and dirty bedding from all cages within the specific room. Samples from sentinels are then submitted to an independent laboratory for serological, microbiological and histopathological evaluations on a predetermined program basis.

Fish: Health monitoring of fish species (currently *Danio rerio*) is performed by either periodic testing of experimental animals that are culled from the population or sick animals. Testing includes microscopic analysis and histopathology.

Rabbits: Preventative health management for the rabbits includes regular examinations by the AV annually or more frequently as indicated, depending on the individual rabbit. Rabbits are on life study, and are closely monitored for dental issues, reproductive issues and body condition scores.

Vendor Animal Program: Every 6 months, for 1-2 weeks, shipments of animals from most commonly used source rooms are selected for testing on arrival. Feces and fur swabs are taken as animals are placed into new cages.

These are sent for PCR testing at IDEXX Bioresearch to ensure that the health report from the vendor is correct. Researchers are informed that the testing will take place, but as it is non-invasive and no procedures are done to the animals except fur swab, the process does not delay the acclimation period. This replaces the previous vendor surveillance program where animals were ordered from commonly used source rooms, euthanized and tested on arrival, reducing the number of animals euthanized each year without compromising facility biosecurity or research integrity.

2. Emergency Care [Guide, p. 114]

a. Describe the procedures to ensure that emergency veterinary care is continuously available for animals during and outside of regular work hours, including access to drugs or other therapeutics and equipment.

Call Lists are posted throughout the facilities in the event of an emergency. Among those numbers listed are those of the Attending Veterinarian and the Project Manager. Both, or their designees, are on call 24/7. The AV and back up veterinarians (on site or on call when the AV is out) always have access to the drugs, analgesics, non-pharmaceutical methods of support for treating animals and facility equipment. The AV provides the specific information of who is serving as backup veterinarian prior to going on leave.

b. Describe the authority of the Attending Veterinarian or his/her designee relative to the emergency treatment of animals in the program.

The Attending Veterinarian or his/her designee has full authority relative to emergency treatment of animals in the program.

3. Clinical Record Keeping [Guide, p. 115]

a. Describe the procedure for maintaining medical records and documenting treatment of ill animals including: clinical laboratory findings, diagnoses, treatments, medical progress records, etc. Identify the species for which individual records are maintained and where such records are kept.

Each rabbit has an individual record that is maintained in the animal holding room by the veterinary staff until the animal is euthanized. Rabbit records are then maintained in the Attending Veterinarian's office for a minimum of three years after the rabbit is euthanized.

Individual records for rodents are maintained whenever an animal health report is made. Fish may or may not have a written animal health report but have a

number assigned for each individual fish with a health issue. An individual animal health report record and animal treatment sheet (if applicable) is maintained in the animal holding suite by the ACS and veterinary staff until the case is closed. Closed records are maintained by the AV.

Additional information for experimental rodents such as weight, food consumption, dose rate, and litter dates may be recorded by the ACS. This information is collected at the intervals requested by investigative staff, and the investigators maintain the information as part of the study record.

b. Identify individual(s) (titles, not necessarily names) responsible for maintaining such records and identify where the records are maintained and who, including the IACUC/OB has access to the records.

The AV and ARPO administrative support maintain and log animal health records for the ARPO. All in the RTPP office have access to the records, and they are available to research staff upon request.

c. Describe the role of the Attending Veterinarian in recordkeeping.

The AV reviews or writes each AHR, is copied on or generates the emails informing the research staff, ACS and vet tech of the AHR, and emails out health updates. The AV collects the paper AHR sheets, records the closure date and outcome of each AHR, and emails this information to the research staff, vet tech and ACS.

- **4. Diagnostic Resources.** Describe available diagnostic methods used in the program including:
 - **a.** In-house diagnostic laboratory capabilities.

A diagnostic laboratory is located in A198. It has the following equipment: incubator, plate counter, dissection scope, microscope, water bath, tissue shaker, fume hood, electronic balance, refrigerator, and down draft table. Facilities and equipment provide the capability to perform parasitological evaluation, gross necropsy and tissue examination. Serum is collected and sent out to a commercial contract lab for serological evaluation. Tissues are submitted to contract labs for histopathological evaluation. Microbiological and other samples are prepared and examined by the in-house lab as well as by an off-site contract lab.

b. Commercially provided diagnostic laboratory services.

Most diagnostic tests (except most parasitology) are performed by outside, commercial laboratories.

Diagnostic Test	Provider
Microbiology	IDEXX RADIL
PCR - pathogens, serology, virology	IDEXX RADIL
Histopathology: mammalian tissue	IDEXX RADIL
Histopathology: fish tissue	ZIRC, IDEXX-RADIL
Parasitology	IDEXX RADIL
Water Analysis	National Testing Labs
Bedding Analysis	Sani-Pure Food Labs
Feed Analysis	Sani-Pure Food Labs
Aflatoxin Testing	Rollins, NC Dept of Agriculture, State Lab
Clinical Pathology	IDEXX RADIL
Urinary Stone Analysis	Minnesota Urolith Center, College of Veterinary Medicine

c. Necropsy facilities and histopathology capabilities.

Necropsy facilities consist of 5 rooms: A198, A390-C, A490-C, A587, and A584. The program does not provide for in-house histopathology.

d. Radiology and other imaging capabilities.

The Program does not have radiography capabilities. An ultrasound machine in a research lab is coordinated between research staff and AV as needed and as possible depending on research use.

5. Drug Storage and Control

a. Describe the purchase and storage of controlled and non-controlled drugs.

The RTPP AV maintains a federal DEA practitioner registration for controlled substances used clinically. The controlled drugs are stored in one of 2 sites within one room. The room is within the vivarium airlock, and requires key card access to enter into the vivarium, and the room door itself has a key and remains locked unless in use. Both sites of drug storage are in this room. One site is a refrigerator for drugs requiring refrigeration. One is in a wall size cabinet that is very heavy. Both sites have in use a locked programmable drug return box. Refrigerator site; One drug return box is located inside a small refrigerator that has been bolted to the wall. The refrigerator has a bolted on padlock assembly. Cabinet site; One drug return box is located inside a large heavy cabinet. The cabinet doors are also padlocked. AV maintains the keys to

the room, the keys to the master locks on the outside of the refrigerator and outside of the cabinet, and the combinations to the drug return boxes.

The Director of the ARPO maintains research registrations (state and federal) for controlled substances use by the ARPO as part of training. All controlled substances for either of these purposes are ordered by the ARPO under these registrations.

Investigators using controlled substances must maintain their own research registrations. The AV does not prescribe drugs for research use.

Controlled substances are stored securely in a lock box in either a locked refrigerator bolted to the floor or in a locked drawer in a locked cabinet too heavy and awkward to move easily. Rooms for both refrigerator and cabinet are kept locked when not occupied. Keys are kept in a separate location.

Non-controlled drugs are kept in a cabinet separate from the controlled substances; the room is locked when not occupied.

b. Describe record keeping procedures for controlled substances.

Registrants using controlled substance maintain the following:

- 1) Name of the substance
- 2) Lot number of substance(s)
- 3) The unit of issue, amount received and date
- 4) SF 222s, order information, shipping information
- 5) The amount used, the date, and the amount on hand, in a Laboratory Rate of Usage log which makes it possible to relate usage records to research notes.
- 5) Records for any of the substances destroyed or disposed of, including Laboratory Rate Usage Sheet. Disposal of unused or expired substances must usually be witnessed by a representative of the state of North Carolina.

D. Surgery [*Guide*, pp. 115-123]

1. Pre-Surgical Planning [Guide, p. 116]

Describe the process(es) used to ensure adequate pre-surgical planning, including: identifying personnel; locating equipment, supplies, veterinary involvement for selecting analgesic and anesthetic agents and facilities; planning; and pre- and post-operative care.

The process used to ensure adequate pre-surgical planning starts with PI requests for veterinary consults on surgical protocols, before an ACUP is formally begun. The AV performs veterinary pre-screening on surgical protocols. The ACUP form specifically asks if the AV was consulted in surgical and post-surgical planning.

Equipment, supplies, analgesic and anesthetic choices are reviewed, and the AV makes suggestions based on the protocol. Recommendations for pre- and post-operative care are discussed with the researcher as well. These are emailed or discussed over phone or in person.

During ACUP review, personnel are identified in the protocol with information on their experience with the relevant procedures. The IACUC reviews the veterinary pre-screen questions and responses from the PI, as well as other questions as they arise during IACUC review. The AV may recommend on site refresher courses on anesthesia, aseptic technique, basic surgical procedures for the research staff involved in a surgical protocol.

2. Surgical Facilities [*Guide*, pp. 116-117, 144-145]

List building name(s) and room number(s) or other locations (coded, if confidential) where surgical procedures are performed. For each, describe:

- the type of species (including rodents, fish, agricultural species, etc.)
- nature of procedure(s) (major/minor/emergency, survival and non-survival, etc.)
- the amount of use [heavy (daily), moderate (weekly), or light]
- major surgical support equipment available (gas anesthesia machines, respirators, surgical lights, etc.)
- facilities for aseptic surgery, surgical support, animal preparation, surgeon's scrub, operating room, and postoperative recovery
- construction features of the operating room(s), including interior surfaces, ventilation, lighting, and fixed equipment used to support surgical procedures and other means of enhancing contamination control

Note: If preferred, the information requested in this section may be provided in Table.

Species; No rabbit surgeries are performed for research purposes. All research related surgeries are on rodents. Clinical surgeries may include rats, mice or rabbits. Some animals are purchased with surgical manipulations including jugular or other catheters and telemeters that had been implanted at vendor. The vendor's surgical information is reviewed during protocol review.

The amount of surgical use for all areas is light.

Nature of surgical procedures performed on site for research purposes: Major survival surgeries include adrenalectomies (performed by hired surgeons), vasectomy, intrauterine insemination, and cranial electrode implantation in rats. Major terminal surgeries currently consist of exploratory laparotomy in use for Basic Surgical Procedures and Aseptic Technique wetlabs and brain surgery involving recording from electrodes placed into specific layers of the brain.

Minor survival surgeries include telemeter implantation in mice. Minor terminal surgeries include catheterization for chemical challenge to animals under deep anesthesia.

Nature of surgical procedures performed on site for clinical purposes: Surgeries for clinical health issues in individual study animals are highly variable and based on need. Examples include tail amputation (mouse or rat), laceration repair, and rabbit ovariohysterectomy. The AV may also do surgery on research animals to repair incision dehiscence or other research related issues.

Most investigative staff performing surgery have their own tools, thermoregulatory support equipment, and gas anesthesia vaporizers. Upon coordination with the AV, the ARPO may also loan out thermoregulatory support equipment (recirculating warm water blankets, forced air warmer ("Bair hugger"), Space Gels and Deltaphase Isotherm pads) and anesthesia equipment. Upon coordination with the AV, the ARPO has provided drape material, sterilization supplies, oxygen tanks and regulators, scavenging equipment, and occasionally surgical instruments. The AV maintains extra in date suture, non-controlled medicines and some similar materials for research staff emergencies.

All vaporizers are calibrated annually by the ARPO.

Surgical areas in the facility have lights, down draft areas, stainless steel work surfaces and appropriate ventilation for surgical areas. There may also be biological safety cabinets. Sterilizers are provided on floors 3, 4 and 5 of the facility for researchers' use. The 4th floor surgical suite has waste gas suction vented to outside. The surgical suites on floors 3 and 4 are built to provide separate areas for surgical preparation, surgery, and recovery.

The following animal facility areas are used for surgeries: Surgical suites;

A390

A490

Procedure rooms;

A390 suite

A490 suite

A584 suite

A587 suite

The surgical suites and procedure rooms may be used for major or minor surgeries, or emergency clinical surgeries. They are used mainly for survival surgery. All surgical areas have light use. No one particular area is designated for any particular surgical procedure; they are designed to be shared spaces.

The following laboratory areas are used for surgeries:

A251 - major survival surgery

A261 - major terminal surgery

A463 – minor terminal surgery

B553 - major terminal surgery

Isoflurane vaporizers and anesthetic machines are mobile and can be moved to different floors and procedural spaces as needed. Other equipment may also be moved to other floors as needed and with reservations. This includes scales, glass bead sterilizers, warm water re-circulating blankets, and rodent induction chambers.

Support equipment by location

Shared spaces:

A390 suite – isoflurane vaporizer/anesthesia machine, warm water re-circulating blanket, glass bead sterilizer, autoclave

A490 suite- isoflurane vaporizer/anesthesia machine, rodent ventilator, autoclave, warm water re-circulating blanket

A587: warm water re-circulating blanket

Laboratory areas:

A251-anesthesia vaporizer/anesthesia machine, warm water re-circulating blankets, pulse oximeter, glass bead sterilizer

A261– warm water re-circulating blanket

A463 – warm water re-circulating blanket

B553 – warm water re-circulating blanket

RTPP does not currently use any specialized considerations to differentiate surgical areas.

3. Surgical Procedures [Guide, pp. 117-118]

a. Describe the criteria used to differentiate major from minor survival surgery, including classification for certain procedures (e.g., laparoscopic technique).

Major surgical procedures qualify by meeting either of 2 requirements; the procedure enters a major body cavity (e.g., cranial vault, thoracic or abdominal cavities) or the procedure permanently impairs an animal physically or

physiologically. These conditions are identified by the AV and IACUC when assessing the ACUP.

Cranial implants, abdominal implants such as telemeters and abdominal vasectomies in rats would be classified as major surgeries. Subcutaneous implants and wound repairs such as skin lacerations would be classified as minor survival surgery.

RTPP does not currently have any laparoscopic procedures.

b. How is non-survival surgery defined?

Non-survival surgery is defined as surgery in which the animal is euthanized before recovery from anesthesia.

- **4. Aseptic Technique** [*Guide*, pp. 118-119]
 - **a.** Describe procedures, equipment, and protective clothing used for aseptic surgery. Include patient and surgeon preparation.

Aseptic procedures begin with preparation of an animal at a separate prep location where the surgical site is appropriately clipped and prepared with povidone iodine or chlorhexidine scrub alternating with alcohol preparation, or Chlorhexidine/alcohol swabs (Chloraprep swabs), with exposure time of 3 minutes total. Once prepared, the animal is placed in a clean field on thermal support. Preparation of the animal is followed by the surgeon donning surgical gear including paper mask, disposable lab coat and sterile surgical gloves. A sterile field using sterile drape should be established and maintained, and all instruments and supplies should be sterile.

b. Describe methods used to sterilize instruments and protective clothing, including a description of approved <u>liquid sterilants</u> and instrument exposure time(s) required for each, if applicable.

Instruments usually are autoclaved before survival surgical procedures. Effectiveness of autoclave sterilization is monitored through review of autoclave indicator tape and an in-pack sterility strip. Autoclaves are tested weekly for effectiveness of sterilization using biological indicators. Disposable and expendable items such as surgical gloves or suture are purchased sterile.

Instruments may be heat sterilized by a hot bead sterilizer for a maximum of 5 separate times before a new autoclaved surgical instrument pack is opened.

There are no liquid sterilants currently in use.

c. Describe methods for instrument re-sterilization between serial surgeries.

If individual autoclaved packs are not available for serial surgeries, it is acceptable to clean instruments' tips with sterile water, then place in a hot bead sterilizer for 15- 20 seconds and cool before use on next rodent. The above method is discussed and demonstrated during the Aseptic Techniques wetlab. Maximum use is 5 times total before a new pack is opened.

d. Indicate how effectiveness of sterilization is monitored.

Autoclave tape is used on the outside of the pack, and strips are used on the inside of the pack. During Basic Surgical Procedures and Aseptic Techniques labs, students are taught to watch for: discoloration of the sterile pack or envelope, rips or tears in the envelopes, and expiration date of the sterile pack, to verify that their sterile pack is, in fact, still sterile.

e. Describe surgical support functions provided by the program to investigators.

Surgical support functions provided by the program to investigators include services from the AV such as: a) consultation on surgical procedures, anesthesia, analgesia, non-pharmacological support (e.g., supplemental heat, alternative bedding and feeds) and b) consultation on any complications arising from surgery or anesthesia, actual surgical assistance (performing surgeries along with research staff) and c) training on surgical technique, anesthesia and monitoring. Further services include assistance with animals as they recover post-operatively, performing surgeries following unexpected outcomes (dehiscences and wound repairs) and assistance in monitoring for complications or unexpected outcomes. The training program also can lend out supplies such as warm water re-circulating blankets, other warming devices, glass bead sterilizer, anesthesia machines and other supplies as needed.

The ARPO has also engaged Charles River Laboratories' Rent-a-Surgeon program to perform surgeries for investigative staff. These surgeries were performed in the A wing animal facility. RTPP staff assisted with animal preparation, monitoring and recovery, the CRL surgeons performed all surgical procedures.

5. Intraoperative Monitoring [*Guide*, p. 119]

Describe monitoring and recording requirements for each species, including the type of record(s) maintained. Also note monitoring of anesthesia during non-survival procedures.

Currently research protocols only involve surgery on mice and rats: the monitoring described below is applicable to both species. For clinical related surgeries on any species, the monitoring is the same, but records are kept by the AV.

The IACUC and AV expect investigators to monitor animals under anesthesia, usually every 15 minutes. Criteria such as response to stimulation (toe pinch), changes in respiratory rate and character, and heart rate are considered the main methods of monitoring for all surgeries regardless of survival. Some researchers also use pulse oximeters and can measure blood pressure once telemeters are implanted.

Records are typically maintained by the research staff. Records will include the animal identification, date of surgery, weight, type and dose of anesthetics and analgesics, and any supplemental doses delivered for anesthesia or analgesia. An anesthesia and analgesia log sheet is used. These are now placed by the research staff either on the animal room door or next to the animal's cage. Many researchers are placing telemeters, and so may have a record of the blood pressure, body temperature or other parameters.

For non-survival surgeries, the same careful assessment of appropriate depth of anesthesia is required. Animals must be euthanized before they emerge from anesthesia

6. Postoperative Care [*Guide*, pp. 119-120]

Describe the postoperative care program, including who is responsible for overseeing and providing the care, types of records maintained (e.g., perioperative), where the records are maintained, etc.

A description of post-surgical provisions is discussed in each ACUP. The monitoring of post-operative animals must be described in the protocol, including who on the research staff will monitor and the frequency of monitoring. The research staff is responsible for provision of analgesics, post-operative monitoring and post-operative care.

The IACUC inquires about the provision of appropriate analgesics or scientific justification for non-use; immediate post-operative monitoring of animals including adequate ventilation, body temperature regulation and hydration; and monitoring after full recovery including food/ water intake, attitude, incisions, and suture/staple removal. Animals are typically monitored closely during the recovery period and at least once daily post-operatively.

The cages of all post-surgical animals are marked with a blue plastic hang tag to readily identify the animals. All post-surgical animals are observed daily by the animal care staff and research staff. The veterinary staff is informed if any problems arise with post-surgical animals. The blue tags are removed by the

research staff when wound clips, staples or sutures have been removed, generally 7 to 10 days post operatively.

Research records of post-operative analgesia, care and other support are maintained by the research staff. In the case of clinical issues, records are kept by the AV.

E. Pain and Distress [Guide, pp. 120-121]

1. Describe how and by whom pain and distress are assessed.

The levels of pain and distress are assessed initially when the ACUP is reviewed by the IACUC. The ORD Health IACUC defines pain and distress as follows: Category C- no pain or distress, or pain or distress that is slight or momentary Category D- pain and distress that is relieved by appropriate measures Category E- Unrelieved pain or distress

Post-procedurally and/or post-surgically, animals are assessed for levels of pain and distress by the research staff, by the animal care staff and the veterinary staff. Cage-side assessments without touching the animal would include looking for alterations in normal behavioral patterns such as reduced exploratory activity, nest building and isolation from cage mates. Feed and water consumption (from water bottles) may be assessed compared to normal cohorts. Other assessments may include picking up the animal for a physical examination, and monitoring for signs of pain, distress or other behavior abnormalities. If behaviors are noted that indicate pain and/or distress, the veterinary staff will discuss findings and recommend options to the researcher. The AV will also speak with the IACUC Chair.

2. Describe training programs for personnel responsible for monitoring animal wellbeing, including species-specific behavioral manifestations as indicators of pain and distress.

All new students and staff must pass Rat, Mouse or Rabbit 101 wet lab class in order to be added to protocols of the relevant species. This lab is taught by the AV. Students may need to take the class several times until they are able to pass. Content of class is discussed with the IACUC. Each time a student passes the class, the AV goes with the student to talk with the PI about the progress. Specific signs of well-being, pain and distress appropriate to the species are discussed during the wet lab. For rabbits, pictures and descriptions are posted on the rabbit room door for all staff. For rodents, an AALAS poster with signs of disease and distress is at the elevator door on every floor in the vivarium.

Animal care staff has their own training. The Veterinary Technician attends and helps out at some 101 classes.

For research labs that do surgery, specific surgery-related clinical issues are discussed at the time of the protocol submission or at any time leading up to the surgeries. Many labs request surgery refresher training before their surgical procedures start.

F. Anesthesia and Analgesia [Guide, pp. 121-123]

1. List the agents used for each species.

Note: If preferred, this information may be provided in Table or additional Appendix.

Rat

Anesthesia

Ketamine- 60- 100 mg/kg/Xylazine- 5- 10 mg/kg IP

Ketamine 50-75 mg/kg/dexmedetomidine 0.5 mg/kg IP

Reversal – Atipamezole 1 mg/kg IP

Isoflurane- to effect, usually 2-5%

Urethane- 1 gm/kg IP

Analgesia

Buprenorphine- 0.01- 0.05 mg/kg SQ or IM BID- QID

Veterinarian only- SR Buprenorphine Dose will check.

Carprofen- 5 mg/kg PO or SQ SID

Meloxicam- 1- 2 mg/kg PO or SQ SID

Bupivicaine- 1 mg/ kg, local infiltration

Lidocaine- 1 mg/kg, local infiltration

Mouse

Anesthesia

Ketamine 80- 100 mg/kg/Xylazine- 5- 10 mg/kg IP

Ketamine 50- 100 mg/kg / dexmedetomidine 1 mg/kg IP

Reversal – Atipamezole at 1 mg/kg

Urethane- 1 gm/kg

Isoflurane- To effect

Analgesia

Buprenorphine= 0.05- 0.1 mg/kg SQ BID

Carprofen- 5 mg/kg PO or SQ SID

Meloxicam- 1-4 mg/kg PO or SQ SID

Bupivicaine- 1 mg/kg local infiltration

Lidocaine- 1 mg/kg, local infiltration

Rabbit

Anesthesia

Isoflurane- to effect

Analgesia:

Meloxicam- minimum dose= 0.2- 0.3 mg/kg PO SID, depending on rabbit and response, may increase to max dose of 1 mg/kg PO SID due to recent literature, or 0.3 to 0.5 mg/kg SQ SID- BID

SR buprenorphine- Dose

Bupivicaine- 1 mg/kg local infiltration Lidocaine- 1 mg/kg, local infiltration

Zebrafish

Anesthesia via immersion

Tricaine (MS-222)- buffered, 200- 250 mg/L, range to effect

Eugenol 600 µM

2. Describe how the veterinarian provides guidance and advice to researchers concerning choice and use of anesthetics, analgesics or other pain moderating methods.

The AV is directly consulted by the researchers in the preparation of ACUPs involving surgical procedures or the use of anesthetics, analgesics or other pain moderating methods. Other, non-surgical procedures that may cause pain or distress are reviewed by the AV for appropriate use, duration, dosages, etc. The AV is accessible at any time for advice on appropriate use of anesthetics and/or analgesics.

3. Describe the monitoring of the effectiveness of analgesics, including who does the monitoring. Include in the description any non-pharmacologic means used to diminish pain and distress.

The researcher describes in the ACUP the method they will use to determine surgical plane of anesthesia, such as non-responsiveness to repeated firm rear toe pinches. The direct use of the anesthetics and analgesics is monitored by the PI and research staff. For mouse surgeries, the AV requires that nestlets are provided after surgery. The absence of some evidence of nesting by the mouse in a day will require additional analgesia for that mouse. For rats, behavioral assessments and weight checks, more than nesting, are used to assess the efficacy of pain relief. The AHT and AV assist and check in on post op patients. The Post Approval Monitor visits laboratories and observes researchers to ensure that anesthetics and analgesics are used properly. The IACUC may visit laboratories and observe researchers to ensure that anesthetics and analgesics are used properly.

Non-pharmacological means of decreasing post-surgical pain and distress can include: pair housing with cagemate for post-operative animals after an appropriate recovery time for rats and mice, soft bedding such as Alpha Dri,

provision of powdered feed or food blocks on the cage floor, extra Enviro-dri nesting material and Nestlets, thermal support, longer sipper tubes and diet supplements such as Diet Gels, Napa Nectar. If clinical issues arise, the veterinary staff will provide additional guidance to the researcher and clinical support to the animals.

4. Describe how the veterinarian(s) and the IACUC/OB evaluate the proposed use of neuromuscular blocking agent to ensure the well-being of the animal.

The AV evaluates the proposed use of neuromuscular blocking agents during the veterinary protocol prescreening process. Comments and questions are discussed with the researcher. The AV and the IACUC review the protocol and responses during ACUP review. Currently, only one procedure in use at RTPP requires the use of a neuromuscular blocking agent. For this procedure, the researcher determines a baseline heart rate after administration of anesthesia and continues to monitor the heart rate for the duration of the procedure If an increase, defined as 30 seconds or longer of a 15% increase in heart rate over baseline, is observed the investigator will administer more anesthesia to the animal. Records are maintained by the lab and are repeatedly checked throughout the terminal procedure.

5. Describe policies and practices for maintaining and ensuring function of equipment used for anesthesia.

Isoflurane vaporizers and anesthesia machines are serviced and calibrated by Eagle Eye Anesthesia Inc. annually. Recommendations are made by the company for different equipment or supplies, or for repairs.

G. Euthanasia [*Guide*, pp. 123-124]

- Describe approved methods of euthanasia, including humane slaughter (for additional guidance, see pertinent <u>AAALAC Reference Resources</u>). Include:
 - consideration of species, age, condition (e.g., gestational period, or neonatal) and
 - location(s) for the conduct of the procedure.

Note: If preferred, this information may be provided in Table or additional Appendix.

Methods for euthanasia conform to the AVMA Guidelines for the Euthanasia of Animals 2013 Edition. Rodents are primarily euthanized by carbon dioxide inhalation via gas cylinder or sodium pentobarbital by parenteral injection (150-250 mg/kg). CO₂ cylinders for rodent euthanasia are available in the following areas A276, A277, A390, A490, A584, A 587, and A198. The procedure for CO₂ euthanasia involves euthanizing animals in home cages whenever possible. Chambers are not pre-charged. The flow rate is set to displace between 10-30%

chamber volume per minute. The chamber is not overcrowded. The chamber is filled for 1-2 minutes and rodents are monitored for an additional 5 minutes in the chamber. Investigators sometimes utilize overdose of inhalant anesthetics depending on research goals and IACUC approval. The location for these may be in investigator laboratories or in shared procedure spaces as above.

Use of a secondary, physical method of confirming euthanasia following use of inhalant anesthesia, CO₂ or sodium pentobarbital is required by the IACUC. Acceptable secondary methods include thoracotomy, exsanguination, other vital organ section, and cervical dislocation.

Euthanasia by physical methods alone such as cervical dislocation or decapitation are used as approved by the IACUC, once training and experience of staff are assessed as competent.

Rodent fetuses that remain in utero are euthanized through euthanasia of the dam. Fetuses that are 15 days of gestation to birth that are removed from the uterus are decapitated upon removal from uterus. If fixation of the fetus is required, fetuses are anesthetized before fixation by hypothermia, injection with a chemical anesthetic, or deep anesthesia of the mother by a chemical that crosses the placenta. Neonatal rodents up to 15 days of age are euthanized by physical methods such as decapitation or cervical dislocation, or by use of injection of chemical anesthetics (sodium pentobarbital), or through CO₂ anesthesia or inhalant anesthesia followed by thoracotomy, exsanguination, or vital organ section. Neonates have a high tolerance for hypoxia; exposure for anesthesia may be prolonged (greater than 20 minutes). For rodents older than 15 days, adult methods may be used. Check with AVMA

Rabbits are euthanized by intravenous overdose of sodium pentobarbital (150-250 mg/kg IV) or CO₂ asphyxiation and thoracotomy.

Zebrafish are euthanized by rapid cooling or by overdose of MS222. The location for this can be A280, A198 or in the investigator laboratory space. Adult zebrafish or zebrafish greater than or equal to 8 days post fertilization (dpf) are euthanized by rapid cooling or MS 222 overdose. Rapid cooling involves immersion into 5:1 ratio of ice to water for at least 20 minutes. Zebrafish may not be in contact with the ice during this time. Overdose with MS222 (200-300 mg/l) by prolonged immersion is another approved method of euthanasia.

Zebrafish larvae that are 4-7 days post fertilization may be euthanized either by rapid cooling, or ice-cold buffered MS222 followed by fixative. For zebrafish embryos less than or equal to 3 dpf, the method of euthanasia is submersion in 1:5 bleach solution. The IACUC has also approved that deeply anesthetized embryos of fry may be placed in fixative. These deviations from AVMA Guidelines were approved based on scientific necessity.

2. Describe policies and practices for maintaining and ensuring function of equipment used for euthanasia.

CO₂ cylinders are replaced as necessary and back-up cylinders are present at euthanasia stations in the facility. Chambers for CO₂ euthanasia are reviewed by the IACUC during inspections. Replacement regulators and some parts are also available in the event of a malfunction.

Ice and breeding tanks are available in A280 for euthanizing zebrafish. (Use of the breeding tank helps keep the fish from coming in contact with the ice.)

Researchers who use decapitation as a euthanasia method are required by the IACUC to regularly maintain the equipment and have redundant equipment in place as a failsafe.

3. Describe the methods used to confirm death of an animal.

Methods used to confirm death of a rodent include cervical dislocation, thoracotomy, vital organ section, exsanguination, and prolonged absence of breathing (absence of visible breathing and lack of heart beat for at least 10 minutes). For rabbits, methods to confirm death include thoracotomy and exsanguination. Physical methods are preferred for confirmation of death.

Zebrafish are left in solution (MS 222 or ice cold water) at least 10 minutes past cessation of opercular movement if visible, followed by immersion in 1:5 bleach solution to ensure death. Fish may also be decapitated or placed in fixative following euthanasia.

IV. Physical Plant [Guide, pp. 133-155]

A. Facilities Overview

Provide a brief introduction to the animal housing and use facilities. Note that this overview should augment the information provided in **Appendix 2** (Summary of Animal Housing and Support Sites), which includes area, average daily census, and person responsible for each site. Please use consistent terminology for the buildings/areas/sites described in the Location section of the Appendix. Please do not repeat information, but supplement the descriptions provided elsewhere to assist the reviewers understanding of the interaction between facilities, special housing locations, and separate procedural areas.

The bulk of the RTP animal housing program is located in a central facility adhering to specific biosecurity requirements. The vivarium is located on the 1st, 2nd, 3rd, 4th, and 5th floors of Building A. Support areas (cage wash, storage, etc) are located on the

first floor. Animal holding suites and procedure rooms are located on floors 2-5. The vivarium has its own dedicated animal care staff including supervisory personnel. The RTPP has full oversight of the facility. The A building core animal facilities are adjacent to research laboratories and are accessed via connecting hallways. The central zebrafish facility is located on floor 2, rabbit housing is on floor 4, and rodent housing is on all floors.

There are 4 potential satellite areas in addition to the A building central facility; these satellites are described in table 17. All satellite areas are reviewed and approved by the IACUC before animals may be housed on site. All satellite areas are required by the IACUC to maintain the same quality of animal care and husbandry as the core facilities. Pertinent records such as temperature and humidity logs and sanitation SOPs are required to be available for review by the IACUC or veterinary staff

B. Centralized (Centrally-Managed) Animal Facility(ies)

In this section, describe each centralized or centrally-managed animal housing and use facility. Include in **Appendix 3** the floor plans of each on 8.5" x 11" or A4 paper. Ensure that the drawings are legible, and the use of each room is indicated (animal housing, procedure room, clean cage storage, hazardous waste storage, etc.). Note that a separate section for describing "satellite housing areas" is included below.

Separately describe **each** Location or Animal Facility, addressing each of the features outlined below (1-8). A complete description of each must be provided; however, common features among locations or facilities may be indicated as such and do not need to be repeated.

- 1. General arrangement of the animal facilities (conventional, clean/dirty corridor, etc.).
- 2. Physical relationship of the animal facilities to the research laboratories where animals may be used.
- **3.** Types of available animal housing spaces used, such as conventional, barrier, isolation/quarantine, hazard containment (infectious, radioactive, chemical), "animal cubicles" or facilities specifically designed for housing certain species such as ponds, pastures, feedlots, etc.
- **4.** Finishes used throughout the animal facility for floors, walls, ceilings, doors, alleyways, gates, etc. (note any areas that are not easily sanitized and describe how these are maintained).
- **5.** Engineering features (design, layout, special HVAC systems, noting exhaust air treatment, if applicable) used in hazardous agent containment.
- **6.** Security features, such as control of entry, perimeter fences, gates, entryways, cameras, guards; identify and describe exceptions for individual facilities or areas incorporating fewer or additional security features than the general features described.
- 7. Consideration for facilities with exterior windows, if applicable, including management of environmental conditions (i.e., temperature and photoperiod control) and potential security risks.

8. Storage areas for flammable or hazardous agents and materials (e.g., disinfectants, cage-washing chemicals, pesticides, fuel).

The Building A vivarium is a restricted access "clean conventional" system with "clean" and "dirty" designated elevators for the movement of personnel, animals, supplies and equipment. Biosecurity barrier training is required before being granted independent access to the building. Mandatory dress and traffic pattern procedures are enforced.

The A building core animal facilities are adjacent to research laboratories and are accessed via connecting hallways. Animals in A building may move back and forth between the labs and the holding rooms. Animals may not leave A building and return to the vivarium.

The 5th floor of the vivarium has suites suitable for biohazard or radiation use and a decontamination facility. These rooms have been used for this type of work, but currently house animals for studies with lower risk levels. No high hazard work has been performed in the RTPP in at least 2 years and there are no active animal protocols for radiation or biohazard work. Areas equipped for high hazard work have separate airlocks for entry/exit, the single pass airflow is negative to the adjacent areas, and the holding rooms are adjacent to a decontamination facility which in turn has direct access to the dirty elevator and dirty cage wash,

Animals are housed in animal holding rooms inside animal suites that are part of the larger facility. Holding rooms are limited to one species. Suites may have more than one species.

Most rodents are house in conventional solid bottom hanging cages with either automatic watering or water bottles (study dependent). There is some IVC caging available. There are some rats who are group housed (up to 10) in large multi-level cages with enrichment. These cages are not biosecure but do allow the rats great opportunity for exercise and socialization.

Rabbits are housed in standard Tecniplast or Lenderking rabbit housing. Our rabbits are all intact, and social housing and unsupervised play has not proven to be appropriate for these rabbits. Rabbits with a history of aggression are housed individually but with visual, auditory and limited tactile contact with conspecifics. Each rabbit spends time each week out in a large "play pen" with padded flooring, hay, assorted manipulata, food, water, and supervised tactile access to compatible conspecifics.

Fish are housed in a single dedicated suite on the 2nd floor of the A building. This suite has been modified to contain the fish life support and research requirements: Two different types of fish housing systems (Tecniplast and Aquaneering), two mini-Mass Embryo Production Systems, redundant RO water supply, a fish procedure room for euthanasia and tissue preparation, an incubator for live feed, refrigerator for

dry feed, water quality testing station, etc. Renovations to improve conditions for rearing fry are slated for the next year and will be reported in the next program description.

The A building vivarium floors are concrete with troweled-on skid resistant antimicrobial methylmethacrylate (MMA) flooring. Fish room floors are provided with trench drains. The floors in the airlocks and lockers rooms are tiled. Walls are concrete masonry block with running bond and covered with water-based epoxy paint.

Doors are painted metal filled with sound attenuation material.

Animal holding rooms, animal procedure space, and sanitation area ceilings are interlocking epoxy-sealed water-proof suspended plaster board.

Corridor ceilings are solid, waterproof, fiberglass-reinforced plastic, suspended ceiling tiles.

Seven Air Handling Units (AHUs) serve all of Building A. Only 5 AHUs are required to meet the building load; however, all AHUs that are available (not down for maintenance) are in service for energy conservation purposes. There is adequate redundancy with respect to the AHUs. Each unit is furnished with 30% efficient prefilters, 95% efficient final filters, energy (heat) recovery coils, clean steam humidifiers, pre-heat coils and chilled water coils. Each animal holding module is equipped with a 99.7% in-line filter assembly, a variable air volume (VAV) airflow control unit and a reheat coil. The building is cooled with chilled water generated at the campus Central Utility Plant and heated with hot water generated in the EPA main mechanical room. Additionally, process steam is generated in the EPA main mechanical room. Backup chilled water, hot water and steam systems are in standby mode, available 24/7 in the event of primary system failure.

There are no exterior windows in the animal holding rooms.

The EPA campus is accessed via roads with gates manned by armed guards. Bollards, strategically placed rocks, trees and fencing supplement campus security. Visitors must provide appropriate proof of identification at the gate before they are permitted to drive onto campus. As not all state licenses are considered "Read ID", visitors should be prepared to either provide "Real ID" or a passport. Vehicles may be subject to search.

Once a visitor is assigned a parking pass and is cleared through the gate, they park in the visitors' lot then must sign in at the guard desk in the main building. Visitors must pass through a screening process including a metal detector and bag X-ray and must register laptops on entry. The guards will issue a visitor's pass and summon the visitor's campus escort.

The entire campus requires key card access for employees, and the vivarium requires key card access to the main airlocks, the elevators, the procedure spaces and the different holding suites.

The campus is patrolled by guards both inside and outside the buildings. There are also security cameras monitored by guards around the clock. Photographs, including via cell phone, are prohibited campus wide.

Chemical storage procedures are based on the chemical. The RTP chemical hygiene plan is available to visitors upon request. The animal facility holding rooms and procedure spaces are provided with either biological safety cabinets or fume hoods, flammable storage, and chemical storage. Chemical storage for cage wash chemicals and disinfectants is provided in cage wash. Hazardous chemicals used in animal studies are not generally stored in the animal facility but are retained in the possession of the individual investigator in appropriate conditions in their labs.

C. Satellite Animal Housing Facilities

In addition to the Appendices summarizing Heating, Ventilation, and Air-Conditioning (**Appendix 11**) and Lighting Systems (**Appendix 16**), summarize animal housing areas that are not centrally-managed or maintained in (**Appendix 17**), "Satellite Animal Housing Areas."

1. Describe the criteria used to determine/define a "Satellite Animal Housing Area," which may include remote housing facilities or laboratories temporarily or consistently housing animals.

A space is considered a satellite animal housing area if animals are held in the area for greater than 12 hours.

2. Describe the process used by the IACUC/OB to authorize, provide oversight of, and ensure compliance with *Guide* standards for the housing of animals outside of centrally-maintained facilities. Include a description of Attending Veterinarian access and physical security.

The AV must have access to all animals in the facility; this includes physical access to all satellite areas.

There are not many satellite facilities in the RTPP, but the IACUC does use a standard satellite application form prior to reviewing the physical location of the satellite. Justification for the satellite facility is provided in both the standard form and explained in the animal care and use protocols that use satellites. Satellites are then included in the semiannual facility inspections by the IACUC. Research staff in satellite areas is required by the IACUC to follow the Guide and maintain the same quality of animal care and husbandry as the core facility, including weekend and holiday care when animals are present. Pertinent records such as temperature and humidity logs and sanitation SOPs are required to be available for review by the IACUC, PAM or veterinary staff.

D. Emergency Power and Life Support Systems

Note: Complete a Heating, Ventilation, and Air-Conditioning (HVAC) Summary (**Appendix 11**) and Lighting Summary (**Appendix 16**) for each Location described in the Summary of Animal Housing and Support Sites (**Appendix 2**).

1. Power [*Guide*, p. 141]

For each Location, Centralized Animal Facility, and Satellite Housing Facility, provide a brief description of the following:

- Availability of <u>emergency power</u> and if so, what electrical services and equipment are maintained in the event the primary power source fails.
- History of power failures, noting frequency, duration, and, if emergency power
 was not available, steps taken to ensure the comfort and well-being of the
 animals present and the temperature extremes reached in animal rooms during
 the failure.

There are generators providing backup power for the RTP campus. Outlets providing this power are either red or marked with red stickers. Equipment may also be hard wired into this backup power. Equipment requiring 3 phase power also can be provided with backup power.

The generators are gas powered. Fuel for approximately one week is generally maintained.

In the past 3 years there has been one serious power outage (spring 2019) and at least one test/maintenance period each year. The recent unplanned outage lasted 4 hours; backup power functioned for most of the facility with some notable exceptions. No animals suffered welfare issues.

- 1. The GFI supporting the backup 3 phase power for one of the fish housing systems tripped and would not provide power. Alternative aeration was provided to the biofilter for the 4 hours without power. The problem GFI has been replaced.
- 2. The batteries providing the memory for the air handling (VAV) boxes across campus had reached the end of their useful lives, and many failed across campus when the power went out. All batteries that failed have been replaced, and the VAV boxes themselves are being upgraded over the next year. Correction began as soon as the VAVs didn't kick on after emergency power came on.
- 3. Animal holding room lighting tied to light timers failed. This lighting has now been tied to backup power.
- 2. Other System Malfunctions. If not previously reported, describe animal losses or health problems resulting from power, HVAC, or other life support system (e.g., individually ventilated cages) failures, and mechanisms for reporting such incidences. AAALAC International Rules of Accreditation (Section 2.f).

There have been no animal losses resulting from equipment malfunction. There was an issue with a sump on a fish rack springing a leak. The sumps on that system are continuous, and to repair the one the entire 5 rack system needed to

be shut down. No animals suffered, but many animals were moved off the rack to different locations.

E. Other Facilities [Guide, pp. 144, 150]

1. Other Animal Use Facilities [Guide, pp. 146-150]

Describe other facilities such as imaging, irradiation, and core/shared behavioral laboratories or rooms. Include a description of decontamination and methods for preventing cross-contamination in multi-species facilities.

There are no shared imaging, irradiation, or other shared core facilities. One researcher does have an ultrasound which the AV and other researchers may access, provided they coordinate with the primary owner/operator.

2. Other Animal Program Support Facilities

Describe other facilities providing animal care and use support, such as feedmills, diagnostic laboratories, abattoirs, etc.

The RTPP does not mill its own feed; feed is purchased commercially. Commercial, independent 3rd party laboratories are used to provide pathology, feed/water analysis and other diagnostic services.

There is a QA facility in the vivarium. Services there include growth and reading of RODAC plates, test ampules for sterilizers, and collection of samples to send out to commercial diagnostic labs for sentinel surveillance.

According to the privacy principles on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, we wish to advise you that the personal data in the Program Description will become part a permanent file owned by AAALAC International, and that can be shared with AAALAC International offices and representatives in order to perform an evaluation of the institution's animal care and use program and provide accreditation services. The institution has the option of exercising rights of data access, rectification, cancellation, and opposition at: accredit@aaalac.org

Appendix 1: Glossary of Abbreviations and Acronyms

Please provide a Table defining abbreviations and acronyms used in this Program Description.

Abbreviation/Acronym	Definition
ACS	Animal Care Staff
ACUP	Animal Care and Use Protocol
AHT	Animal Health Technician
ARPO	Animal Resources Program Office
AU	Annual Update
AV	Attending Veterinarian
BC	Branch Chief
BAS	Building Air System
CPHEA	Center for Public Health and Environmental Assessment
DD	Division Director
EPA	Environmental Protection Agency
FOH	Federal Occupational Health
FSCB	Facilities Safety and Compliance Branch
IACUC	Institutional Animal Care and Use Committee
10	Institutional Official
ISHEM	Initial Safety, Health and Environmental Monitoring (training)
OMSP	Occupational Medical Surveillance Program
ORD	Office of Research and Development
PAM	Post Approval Monitor
PHITD	Public Health and Integrated Toxicology Division
PI	Principle Investigator
RSCD	Research Support and Compliance Division
RTP	Research Triangle Park, NC
RTPP	Research Triangle Park Program: inclusive of the IACUC, ARPO, ACS and Research Staff
SHEM	Safety, Health and Environmental Management
VVC	Veterinary Verification and Consultation

Appendix 2: Summary of Animal Housing and Support Sites

Briefly summarize in the following Table the animal facility or facilities, noting the number of areas in which animals are housed (buildings, floors, farms, satellite housing facilities, etc.), the total square footage/metres (or acreage) for animal care and use, and the total square footage/metres (or acreage) for necessary support of the animal care and use program covered by this Description (water treatment plant/area if housing aquatic or amphibian species, cagewashing facilities, service corridors, etc. and additional areas to be considered are enumerated in the *Guide*). Detailed information for satellite housing facilities is requested in Appendix 17. Include only one line entry for satellite housing facilities in this table to provide the total square footage for all satellite housing areas listed in appendix 17. If more than one facility/site, note the approximate distance (yards/miles or meters/kilometers) to each facility from a reference point such as from the largest animal facility. A campus/site map (with a distance scale) may be included as an additional Appendix (Appendix 2.1) to provide this information. See Instructions, Addendum A - Animal Facility Square Footage/Meters Compilation Form for guidance in calculating the size of your animal care and use program.

		Animal I	lousing and Supp	oort Sites		
Location (building, site, farm name, etc. ^a)	Distance from main facility ^b	Approx. ft ² , m ² , or acreage for animal housing	Approx. ft ² , m ² , or acreage for support or procedures	Species housed	Approx. Daily Animal Census by species	Person in charge of site
Building A EPA Main Campus	North end EPA Main Campus	15,568 ft ² (5 Floors)	21,673 ft ² (5 Floors)	rats, mice, fish, rabbits	Rats: 1,100 Mice: 500 Fish: 7,500 Rabbits: 8	Exemption 6
HiBay Satellite EPA Main Campus (this facility has not been used in approximately 2 years)	South end of main campus	109 ft ² (1 Floor)	0	rats, mice	Rats 0 Mice 0	Exemption 6 Exemption 6

Appendix 2: Summary of Animal Housing and Support Sites

		Animal I	lousing and Supp	ort Sites		
Location (building, site, farm name, etc. ^a)	Distance from main facility ^b	Approx. ft ² , m ² , or acreage for animal housing	Approx. ft², m², or acreage for support or procedures	Species housed	Approx. Daily Animal Census by species	Person in charge of site
Satellite Housing Facilities Total (Expand in Table 17)		616 ft ²	0			

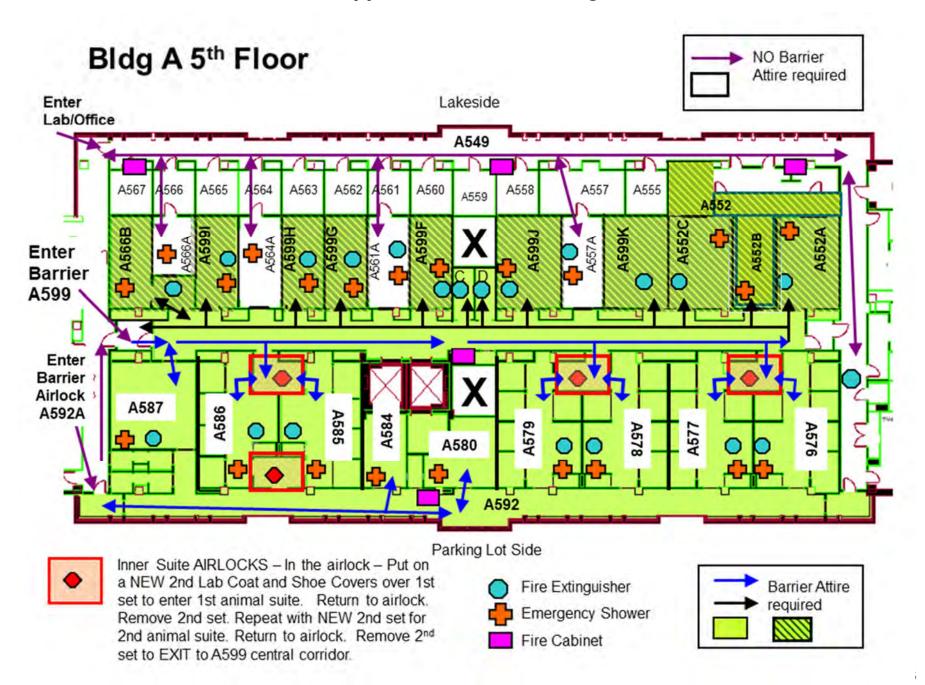
Totals:	16,293 ft ²	21,673 ft ²	
Total animal housing and	37,966 ft ²		
support space:	(please s	pecify ft ² or m ²)	

^aPlease state name and/or use acronyms described in **Appendix 1** for building names, if not coded for confidentiality. ^bCampus or site map(s) may also be provided in lieu of this information.

Appendix 3: Line Drawings

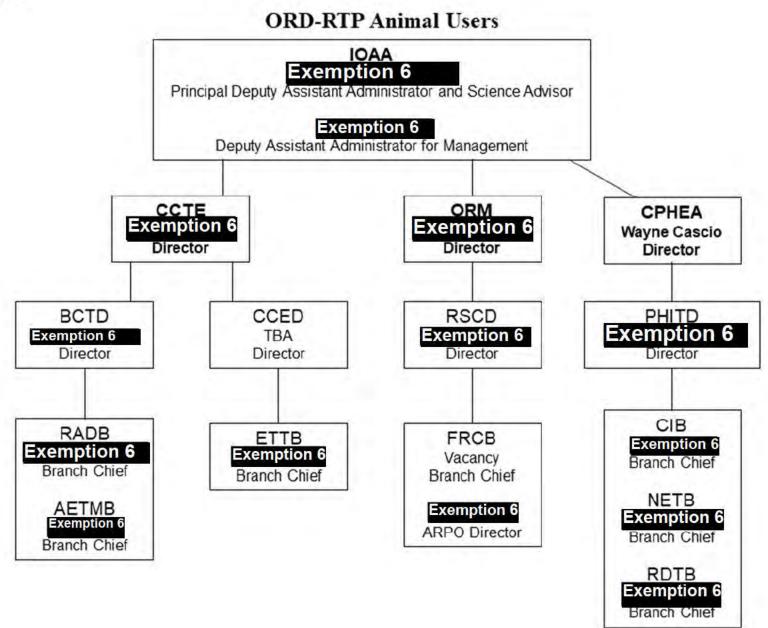


Appendix 3: Line Drawings



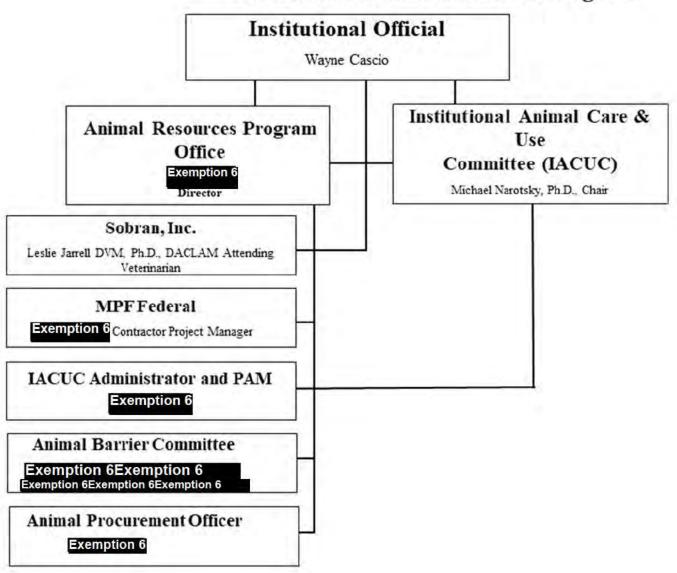
Provide an accurate, current, and detailed organization chart or charts that detail the lines of authority from the Institutional Official to the Attending Veterinarian, the IACUC/OB, and personnel providing animal care. If applicable, include personnel responsible for managing satellite housing areas/locations and depict the reporting relationship between the Attending Veterinarian and other(s) having a direct role in providing veterinary care.

Appendix 1a.



Appendix 1b.

ORD-RTP Animal Resources Program

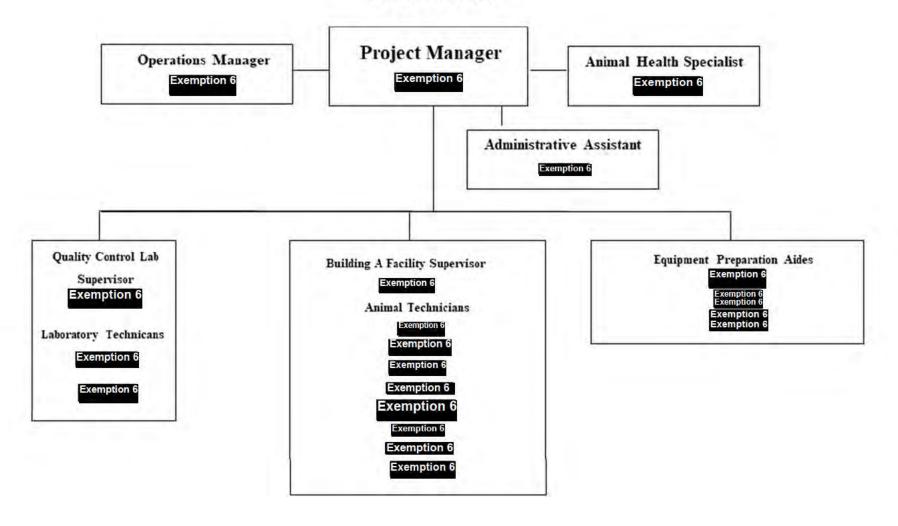


ŧ.

Appendix 1c.

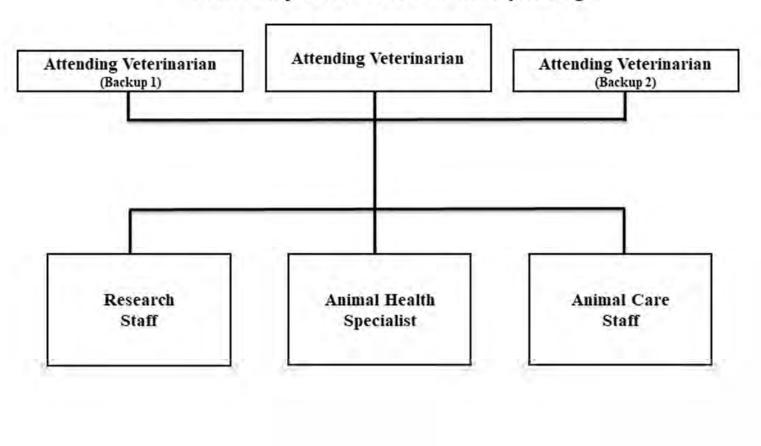
Animal Care Contractor Staff

MPF Federal



Appendix 1d.

Veterinary Care - Role and Reporting



i

Provide an accurate, current, and detailed organization chart or charts that detail the lines of authority from the Institutional Official to the Attending Veterinarian, the IACUC/OB, and personnel providing animal care. If applicable, include personnel responsible for managing satellite housing areas/locations and depict the reporting relationship between the Attending Veterinarian and other(s) having a direct role in providing veterinary care.

In order to assist the site visitors in their evaluation of the animal care and use program, please provide the information requested below. Information should be provided for all animals approved for use in research, teaching or testing, including those which may be used or housed in laboratories outside the animal care facility. Of particular interest is information on those animals which are used in research projects involving recovery surgical procedures, behavioral or other testing requiring chairing or other forms of restraint, or exposure to potentially hazardous materials. An alternate format is acceptable as long as the information requested is provided.

Principle Investigator names have been replaced with numbers. All EPA documents are FOIA-able. A key is available upon request.

			Species	Total	Pain &	Special Considerations (use checkmark if applicable)						
Project/Protocol Title		Principal Investigator		Number of Animals Approved	Distress Category (1)	SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)	
Vendor Disease Surveillance for Mice, Rats and Fish	19-11-001	1	Multiple	954	С	No	No	No	No	No	No	
Thyroid Disruptors and Neurodevelopmental Outcomes in Rat	20-01-001	6	Rats	6,377	D	No	No	No	No	Yes	Yes	
Testing predicted chemical reactivity-based neurotoxicity to develop possible Adverse Outcome Pathways (AOPs) in rats	20-01-002	11	Rats	464	E	No	No	No	Yes	No	Yes	
Development of Red Blood Cell Protocols for Air Pollution Studies in Rats	20-05-001	4	Rats	122	С	No	No	No	No	No	Yes	
The Effect of Prenatal Ozone Exposure and	20-06-001	3	Rats	764	E	No	No	Yes	No	Yes	Yes	

Sand Carrie 1			Species	Total	Pain &	Special Considerations (use checkmark if applicable)							
Project/Protocol Title	IACUC/OB Number	Principal Investigator		Number of Animals Approved	Distress Category (1)	SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)		
Postnatal Dietary Influences on Later Life													
Oleic acid-induced Pulmonary and Systemic Stress and the Role of Increased Iron Availabilty in Rats	20-06-002	22	Rats	182	E	No	No	No	No	Yes	Yes		
Establish and Maintain a Breeding Colony of Zebrafish (Danio rerio)	20-07-001	18	Fish	13,375	С	No	No	No	No	No	Yes		
Assessment of disinfected drinking water and disinfection by-products for developmental and reproductive toxicity in rats	20-07-003	16	Rats	302	с	No	No	No	No	No	No		
Assessment of the oral bioavailability of cyanotoxins in the mouse	20-08-001	12	Mice	184	E	No	No	No	No	Yes	No		
Using Zebrafish Embryos to Test for Developmental Neurotoxicity	20-08-003	18	Fish	133,574	С	No	No	No	No	Yes	Yes		
Non-invasive characterization of	20-08-004	14	Mice	6	С	No	No	No	No	No	No		

				Total	Pain &	(1	Speci use che	ial Con ckmar			le)
Project/Protocol Title	The state of the s	Principal Species Investigator	THE RESERVE OF THE PROPERTY OF	Distress Category (1)	SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)	
cardiac function in mice with ECGenie system											
The effect of COX-2 inhibition by environmental toxicants on sexual differentiation of the hypothalamus in the rat	20-09-001	20	Rats	399	С	No	No	No	No	yes	No
Developmental toxicity assessments of drinking water contaminants in rats	20-09-002	16	Rats	21,828	С	No	No	No	No	Yes	No
Characterization of the effects of putative sodium iodide symporter (NIS) inhibitors on endocrine and reproductive function in male and female rats	20-10-001	15	Rats	1,388	С	No	No	No	No	Yes	No
Cylindrospermopsin toxicity studies in mice using the oral route.	21-04-001	2	Mice	360	С	No	No	No	No	Yes	No
Adverse health effects of exposure to	21-04-002	2	Mice	1,532	E	No	No	No	No	Yes	No

Service of the		IACUC/OB Principal Number Investigator		Total	Pain &	Special Considerations (use checkmark if applicable)							
Project/Protocol Title			Species	Number of Animals Approved	Distress Category (1)	SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)		
algal/cyanobacterial toxins alone or with other environmental contaminants in the mouse													
Metal and metalloid bioavailability in the laboratory mouse	21-04-003	21	Mice	2,232	С	No	No	No	No	Yes	No		
The Effect of Inadequate Housing Conditions as a Factor of Psychosocial Stress in the Worsening of Air Pollution-induced Cardiopulmonary Dysfunction in Mice	21-05-001	10	Mice	580	D	Yesl	No	No	No	Yes	Yes		
Early-life stress as modifier of air pollution health effects in rats	21-08-001	22	Rats	134	E	No	No	No	Yes	Yes	Yes		
Impacts of perinatal exposure to non-chemical and chemical stressors on neurodevelopment in rat offspring	21-08-002	11	Rats	894	E	No	No	No	Yes	No	Yes		
Developmental Toxicity of	21-08-003	18	Fish	12,096	С	No	No	No	No	Yes	Yes		

			Species	Total	Pain &	(1	Speci use che	ial Con			le)
Project/Protocol Title	Number I	Principal Investigator		Number of Animals Approved	Distress Category (1)	SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
Perfluorinated Chemicals in Zebrafish											
Use of ovarian follicle culture and ovulation studies to assess the effects of environmental and pharmaceutical chemicals on female reproductive function in the rat.	21-09-001	20	Rats	840	С	No	No	No	No	Yes	No
In Vitro / Ex Vivo Male Reproductive Assessments in the Male Rat	21-09-002	13	Rats	1,854	D	Yes	No	No	No	No	Yes
Methods for high- throughput assessment of chemical effects on neurodevelopment using cultured neurons from rats in vitro	21-12-002	19	Rats	1,716	С	No	No	No	No	No	Yes
Fetal and postnatal assessment of in utero and lactational exposures to endocrine disrupting chemicals in rats	22-03-001	9	Rats	5,139	С	No	No	No	No	Yes	Yes

			Species Num Ani	Total	Pain &	(1	Speci use che	al Con			le)
Project/Protocol Title	The state of the s	Principal Investigator		Number of Animals Approved	Distress Category (1)	SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
Hazardous Air Pollutant Effects in a Mouse Model of Allergic Asthma	22-03-002	5	Mice	400	С	No	No	No	Yes	Yes	Yes
NHEERL Animal Handling, Use and Procedures Training	22-03-003	8	Multiple	1,109	D	No	No	No	No	No	No
Effect of Chronic Allergic Airways Disease on Cardiovascular Function in Rats	22-03-004	4	Rats	212	D	Yes	No	No	Yes	Yes	Yes
Validation of sperm fertility biomarkers in the rabbit	22-04-001	13	Rabbits	19	С	No	No	No	No	No	No
The effect of diet on cardiopulmonary health and subsequent responses to depleted housing conditions and air pollution exposure in rats	22-05-001	10	Rats	2,484	D	No	No	No	No	Yes	Yes
Comparative cardiopulmonary toxicity of ambient and combustion emission particles in mice	22-06-001	7	Mice	960	С	No	No	No	No	No	Yes

			Species	Total	Pain &	(1	Speci use che	al Con			le)
Project/Protocol Title	IACUC/OB Number	Principal Investigator		Number of Animals Approved	Distress Category (1)	SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
Animal Research Program Office Holding Protocol for Rats, Mice, Rabbits and Fish	22-06-002	8	Multiple	300	В	No	No	No	No	No	No
Protein Adduct Formation as a Potential Adverse Outcome Pathway for Neurotoxicity in Rats: Role of Hard and Soft Acids	22-06-003	17	Rats	78	С	No	No	No	No	No	Yes
Hazardous Air Pollutant Effects in a Mouse Model of Allergic Asthma	22-03-002	5	Mice	400	С	No	No	No	Yes	Yes	Yes
Comparative Toxicity of Combustion Emissions from Synthetic Structures in Mice	22-08-001	5	Mice	104	С	No	No	No	Yes	No	Yes
Sentinel Animal Disease Surveillance- Rat, Mouse, Fish, Rabbit	22-08-002	8	Multiple	3,768	С	No	No	No	No	No	No
Role of Sleep in the Cardiovascular Responses to Air Pollution in Rats	22-08-003	4	Rats	40	D	Yes	No	No	No	No	Yes

Title	IACUC/OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)						
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)	
The effect of paternal biomass exposure on pregnancy outcomes			Rats		E	Yes	No	No	Yes	No	Yes	
in rats	22-08-004	3		246								

⁽¹⁾ If applicable, please provide a description / definition of any pain/distress classification used within this Appendix in the space below. If pain/distress categories are not used, leave blank.

- (2) Survival Surgery (SS)
- (3) Multiple Survival Surgery (MSS)
- (4) Food or Fluid Regulation (FFR)
- (5) Prolonged Restraint (PR)
- (6) Hazardous Agent Use (HAU)
- (7) Non-Centralized Housing and/or Procedural Areas (NCA), i.e., use of live animals in any facility, room, or area that is not directly maintained or managed by the animal resources program, such as investigator laboratories, department-managed areas, teaching laboratories, etc.

Pain/Distress Classification Description/Definition, if applicable:

The RTPP follows the USDA Pain/Distress classification system

In the Table below, provide an approximate annual usage for all species: Numbers are for FY 18; FY19 data is still coming in, but the numbers will be roughly comparable.

Animal Type or Species	Approximate Annual Use
Zebrafish (Danio rerio) embryos/fry (experiments)	20,000
Zebrafish (Danio rerio) Adults (breeding)	6,500
Rats	4,431
Mice	2003

Animal Type or Species	Approximate Annual Use
Rabbits	9

[Create additional rows by pressing TAB in the bottom-right box.]

Provide a *blank* copy of form(s) used by medically-trained personnel to review individual health assessment, individual risk assessment, health history evaluation, health questionnaire, periodic medical evaluation, etc. If form(s) are not used, include a description of how such evaluations are performed in the Program Description (Section 2.I.A.2.b.ii.1).d), Section 2 (Description). I (Animal Care and Use Program). A (Program Management). 2 (Personnel Management). b (Occupational Health and Safety or Personnel). ii (Standard Working Conditions and Baseline Precautions). 1) (Medical Evaluation and Preventive Medicine for Personnel). d).



Environmental Protection Agency EPA National Medical Evaluation Form

Privacy Act Statement

The collection and use of this information is authorized by 5 U.S.C. 7901 (Health Services Programs) and 20 U.S.C 657 (Occupational Health and Safety; Record Keeping). The information will become part of your official Employee Medical File, and will be used to assist Federal Occupational Health in carrying out its occupational health services responsibilities under one or more interagency agreements with our employee agency, and for other official purposes and routine uses as described in Privacy Act systems notice OPM/GOVT-10 (Employee Medical File System Records). Providing the requested information is voluntary. Not providing the information may affect the availability and quality of health services rendered to

you and may also affect the completeness of information used by your agency in making determinations of medically-related employment decisions.

EPA Policy Statement

As per EPA Order 1460.1, Occupational Medical Surveillance Program, all EPA programs and regions must support a comprehensive, exposure-driven Occupational Medical Surveillance Program (OMSP). Employee enrollment in the OMSP is determined solely by defined criteria (EPA Order 1460.1, Section 4a). In order to comply with the Occupational Safety and Health Act of 1970, the Agency requires all employees who have been selected for inclusion in the OMSP to comply with and participate in the program. Failure to comply with the requirements that are incorporated or referenced in EPA Order 1460.1, or cited in associated guidance, may result in progressive disciplinary actions, as prescribed by Agency policy and the U.S. Office of Personnel Management (OPM). Administrative actions taken, based on medical recommendations, will be consistent with Section 501 of the Rehabilitation Act of 1973, as amended.

EPA NATIONAL MEDICAL EVALUATION FORM

National Occupational Medical Surveillance Program



EMPLOYEE TO COMPLETE ALL SHADED AREAS OF FORM BEFORE APPOINTMENT.

Health Center – Attach COPY of screening, diagnostic, and laboratory tests and a COPY of this form for final medical review. Retain all originals in employee file.

SS# (last four digits only):	Gender: Male Female	Date of Birth:		
Employer's Address:				
Client's Home Address:				
Supervisor Name:	Work Phone #:	[SHEMP Manager input, has been expanded. FOH Health Unit must review page 11 for SHEM Manager's recommended exam frequency and additional testing.]		
SHEMP Manager:	Work Phone #:			
Position Title:				
Client Name:	Work Phone #:	Health Unit Phone:		
	(Employee to complete)	Health Unit Location:		

BASELINE / EXIT CORE EXAM* OCCUPATIONAL HEALTH EVALUATION

Required services:

- · FOH Profile, Blood and Urine
- EKG
- · Vision Screening (Best Vision)
- Chest X-Ray PA
- General Physical Examination (Comprehensive Exam)
- · General Medical History
- Audiometry

If indicated services (per work order):

- Spirometry
- Stress test
 - Immunizations
 - MCM program prescription
 - Voluntary Exercise Program (VEP)
 - DuoDote injector clearance

PERIODIC CORE EXAM * OCCUPATIONAL HEALTH EVALUATION

Required services:

- FOH Profile, Blood and Urine
- Vision Screening (Best Vision)
- · General Physical Examination (Comprehensive Exam)
- General Medical History

If indicated services (per work order):

- Audiometry
- Spirometry
- EKG
- Stress test
- Medical Counter Measures (MCM) program prescription
- Voluntary Exercise Program (VEP)
- DuoDote injector clearance
- Chest X-Ray PA

MEDICAL SURVEILLANCE - SPECIAL PROFILES

(SHEM check all that apply)

(Nurse to complete selected profile testing per work order)

- □ Animal Handler
- □ Clean Air Inspector/Enforcement Officer
- □ Diver □ Hazmat Diver (30 days potential exposure per year, or based upon known high exposure potential from Unit Dive Officer (UDO)).
- □ Emergency Response and On-Scene Coordinator
- ☐ Federal Insecticide Fungicide & Rodenticide Enforcement

Officer (FIFRA)

- ☐ Field Sampling Employee
- □ Lab Employee
- ☐ National Emission Standard for Hazardous Air Pollutants

(NESHAPS)/ Asbestos Hazard Emergency Response (AHERA)

☐ National Pollutant Discharge Elimination System Inspector

(NPDES)

- ☐ Pesticide Laboratory Employee/CWA Lab Employee
- □ Radiation Employee
- ☐ Remedial Project Manager
- ☐ Resources Conservation & Recovery Enforcement Officer

(RCRA)

	☐ Toxic Substances Control Enforcement Officer (TSCA) ☐ Underground Storage Tank Inspector (U.S.T.) ☐ Wetlands Employee

^{*} This examination does not substitute for a periodic health examination conducted by your private provider. This examination is being conducted for occupational purposes. Form updated: 8/22/2019

Animal Handler

Periodic Core Exam

• Respirator Clearance (if indicated on pg. 11)

Clean Air Inspector/Enforcement Officer

Baseline/Exit Core Exam

• Respirator Clearance (if indicated on pg. 11)

Diver/HazMat Diver

Baseline/Exit Core Exam

- Respirator Clearance (if indicated on pg. 11)
- MCM Prescription (HazMat Diver only) (Baseline only)
- DuoDote injector clearance (HazMat Diver only) (Baseline only)
- Voluntary Exercise Program (VEP) (HazMat Diver only) (Baseline only)

Periodic Core Exam

- Respirator Clearance (if indicated on pg. 11)
- MCM Prescription (Hazmat Diver only)
- DuoDote injector clearance (HazMat Diver only)
- Voluntary Exercise Program (VEP) (HazMat Diver only)

Emergency Response, On-Scene Coordinator

Baseline/Exit Core Exam

- Respirator Clearance (if indicated on pg. 11)
- Voluntary Exercise Program (VEP) (Baseline only)
- DuoDote injector clearance (Baseline only)
- MCM Prescription (Baseline only)

Periodic Core Exam

- Respirator Clearance (if indicated on pg. 11)
- MCM Prescription
- DuoDote injector clearance
- Voluntary Exercise Program (VEP)

Federal Insecticide, Fungicide, and Rodenticide Enforcement Officer (FIFRA)

Periodic Core Exam

• Respirator Clearance (if indicated on pg. 11)

Field Sampling Employee

Baseline/Exit Core Exam

- Respirator Clearance (if indicated on pg. 11) Periodic Core Exam
- Respirator Clearance (if indicated on pg. 11)

Lab Employee

Baseline/Exit Exam

- Respirator Clearance (if indicated on pg. 11)
 Periodic Exam
- Respirator Clearance (if indicated on pg. 11)

National Emission Standard for Hazardous Air Pollutants (NESHAPS) / Asbestos Hazard Emergency Response Enforcement Officer (AHERA)

Baseline/Exit Core Exam

- Respirator Clearance
 Periodic Core Exam
- Respirator Clearance

National Pollutant Discharge Elimination System Inspector (NPDES), Underground Storage Tank Inspector (UST)

Periodic Core Exam

• Respirator Clearance (if indicated on pg. 11)

Pesticide/Chemical Warfare Agent (CWA) Lab Employee

Baseline/Exit Core Exam

• Respirator Clearance (If indicated on pg. 11)

Pesticide/Chemical Warfare Agent (CWA) Lab Employee (continued)

Periodic Core Exam

- Respirator Clearance (If indicated on pg. 11)
- DuoDote injector clearance (CWA only)

Radiation Employee

Baseline/Exit Exam

- Respirator Clearance (If indicated on pg. 11)
 Periodic Exam
- Respirator Clearance (If indicated on pg. 11)

Remedial Project Manager

Baseline/Exit Core Exam

- Respirator Clearance (if indicated on pg. 11)
 Periodic Core Exam
- Respirator Clearance (If indicated on pg. 11)

Resources Conservation and Recovery Enforcement Officer (RCRA)

Baseline/Exit Core Exam

- Respirator Clearance (if indicated on pg. 11)
 Periodic Core Exam
- Respirator Clearance (If indicated on pg. 11)

Toxic Substances Control Act Enforcement Officer (TSCA)

Baseline/Exit Core Exam

- Respirator Clearance (if indicated on pg. 11) Periodic Core Exam
- Respirator clearance (if indicated on pg. 11)

Wetlands Employee

DuoDote injector clearance (CWA only) (Baseline only)	Periodic Core Exam
	Respirator clearance (if indicated on pg. 11)
	• Respirator clearance (ii indicated on pg. 11)

SPECIALTY EXAMINATION SUMMARY — Work order may specify additional testing; SHEMP manager provides rationale for "if indicated testing" on pg 11

The second secon	complete		2 2 2 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1				urse of doctor to complete as indicated)
VASCULAR			CARDIO/PL	JLMONARY			CHEST X-RAY
	Yes	No	(Ex	amining phys	sician to comp	lete)	(Nurse to complete)
Enlarged superficial veins							
Hardening of the arteries			Normal Ab	normal			Last PA chest X-ray: Date
High blood pressure			0 0	EKG (at	tach with interp	retation)	
Stroke			0 0	1 Lungs/c	hest (includes b	reast)	Result: □ Normal □ Abnormal
Transient Ischemic Attack (TIA)			0 0	J Heart (th	hrill, murmur)		Comments:
Aneurysms (dilated arteries)			0 0	Vascula	r		Comments.
Poor circulation to hands and feet							
White fingers with cold/vibration			Pulmonary	Function Tes	sting: (attach co	ppy)	
RESPIRATORY			% Predicted	% Predicted	% Predicted	% Predicted	(Nurse to complete)
	Yes	No	FVC	FEV1	FEV1/FVC	FEF 25-75	Height Weight
Asthma (include exercise induced asthma)					TEVIII I	TEI EU IU	
Bronchitis							Blood pressure mm/hg Pulse
Emphysema							/min
Acute or chronic lung infections			(in liters)				Respirations /min Temp (if indicated)
Wind pipe or lung surgery			(in itters)				Hespirations/min_remp (ii indicated)_
Collapsed lung			Comments/f	lindings:			IMMUNIZATIONS (with dates)
Scoliosis (curved spine) with						Tetanus-diphtheria (Td):	
breathing limitations						Influenza:	
History of tuberculosis			Position dur	ing test: ☐ Sta	anding	tting	Hepatitis A:
							Hepatitis B:

HEART			CARDIAC RISK PROFILE (Nurse to complete)	CORONARY RISK FACTORS		
71	Yes	No		(Nurse to comple	ete)	
Heart pain (angina)			Chol		Yes	No
Heart rhythm disturbance				Blood pressure ≥ 145/90		
History of heart attack			HDL	Fasting glucose ≥ 120 mg/dl		
Organic heart disease		0	LDL	Total cholesterol ≥ 200 mg/dl		
(including: prosthetic heart valves,				Obesity		
mitral stenosis, heart block, pacemaker Wolf Parkinson White (WPW) syndrome			Trig	No regular exercise program □		
Heart surgery		п	Gluc	Currently smoking		
Mitral valve prolapse				1000		
Palpitations (irregular heart beat)						
Sudden loss of consciousness		п				
PHYSICAL ACTIVITY OR EXERCISE P	ROGRAM	(Check one)	(Employee	to complete)		
Intensity: □ Low □ Moderate	□ Higl	h	Have you been hospitalized or had surgery in the past If yes, please describe:	2 years? ☐ Yes ☐ No		
ActivityFrequency	_ (days pe	er week)				
Duration (minutes)			ALLERGIES:			
			MEDICATIONS: List all medications (prescription and	over-the-counter) you are currently to	aking:	

WELLNESS/HEALTH PROFILE	RESPIRATOR CLEARANCE QUESTIONS	U.S. EPA DIVER QUESTIONS		
Smoking History This information is needed since smoking increases your risk for lung cancer and several other types of cancer, chronic bronchitis, emphysema, asbestos-related lung diseases, coronary heart disease, high blood pressure, and stroke.	☐ My position does not require the use of a respirator (if selected, <u>DO NOT complete</u> questions below) (NO PERIODIC SPIROMETRY IF THIS CHOICE INDICATED, ONLY BASELINE AND EXIT) ☐ My position may require the use of a respirator (if selected, <u>DO</u> complete questions	List type or types of breathing apparatus/regulators used while diving: Level of work effort (select one): Light		
Please check your smoking status and complete that section:	below) (PERFORM SPIROMETRY IF THIS CHOICE INDICATED)	Extent of usage:		
□ Never Smoked		☐ On a daily basis		
☐ Current Smoker	Type of respirator do/will you use:	☐ Occasionally - but more than once a week		
Number of cigarettes per day Number of cigars per day	☐ Cartridge ☐ Air supply ☐ SCBA How often do you use a respirator:	☐ Rarely - or for emergency situations only		
Number of pipe bowls per day	☐ Daily ☐ Weekly ☐ Monthly ☐ < two times a year Effort while using respirator:	Length of time of anticipated effort in hours:		
Total years you have smoked Former Smoker Number of cigarettes per day	□ Light □ Moderate □ Heavy Hazards present during use: □ High altitude □ Temperature extremes □ Confined spaces Respiratory Protection Program Information:	Special work considerations (i.e., extra cold water, polluted water, deep diving etc.):		
Number of cigars per day ————	☐ Suspended/Inactive ☐ No Longer Required ☐ Pending/Standby	DIVING HISTORY		
Number of pipe bowls per day	Type & Fit Test Date:	How many dives (wet) do you perform per year (on average)?		
Total years you smoked	☐ MSA / _ / _ ☐ North _ / _ / _ ☐ Scott _ / _ / _ ☐ Other _ / _ / _ Comments (Size, Model, Half/Full Face):	How many chamber dives per year?		

☐ Chronic exposure to environmental tobacco smoke	Have you ever had or do you now have a	ny of the	ollowing?						
Alcohol/Drug Use	Please check all that apply and use the space responses.	ce below to	comment	on positive	How deep do you dive, on average?				
What is your average alcohol consumption in a week?		Yes	No	Do you perform moderate or heavy physical labor	at depth?				
drink(s)	Persistent cough				☐ Never ☐ Rarely ☐ Sometimes ☐ Usually [☐ Always			
(1 drink = 12 oz. beer, 1 glass wine, or 1.5 oz. liquor)	Heart trouble					10700			
How often do you drink alcohol? ☐ Weekdays ☐ Weekends ☐ Both	Shortness of breath				History of:				
	History of fainting or seizures				Decompression sickness				
Do you use recreational drugs? ☐ Currently ☐ Previously ☐ Never	Fear of tight or enclosed spaces				Arterial gas embolism	_			
	Sensation of smothering				Ear barotrauma				
ANIMAL HANDLER QUESTIONS	Heat exhaustion or heat stroke				Pulmonary barotrauma				
List type of occupational animal exposure:	Contact lenses or eyeglasses				Marine envenomation				
☐ Non-human primates and their tissue/fluid ☐ Bats	Other conditions that might interfere with				Disease from exposure to cold/heat				
☐ Pregnant mammals (non-rodents) ☐ Birds	respirator use or result in limited work activity	ty							
☐ Venomous animals (including snakes)	Client comments regarding positive response	es to resp	rator cleara	Have you ever been restricted in your diving duties due to a medical					
☐ Wild-caught mammals and birds	questions:			Have you ever been restricted in your diving du condition?	ities due to a n	nedical			
☐ Standard lab animals (usual EPA exposure = mice, rats, rabbits, dogs,				☐ Yes ☐ No					
cats, pigs, etc.)	-				If yes, explain:				
☐ Other species									
					Have you ever required hyperbaric oxygen ther	apy?			
Medical history concerns:					□ Yes □ No				
☐ Known allergies or suspected allergies to animals	DERMATOLOGY		Yes	No	If yes, explain:				
☐ Chronic health problems such as diabetes	Sun sensitivity		_	_			-		
☐ Serious renal or liver disease	Allergic dermatitis to rubber								
☐ Valvular heart disease	History of chronic dermatitis		0		Section 1997				
☐ Immune system deficiencies or other limitations to your ability to fight	Active skin disease Moles that change in size or color				MENTAL HEALTH	Yes	No 🗆		
off	Wides that change in size of color		-	-	Current psychological/psychiatric condition	- E			
disease					Depression				
☐ Current therapy with high dose steroids, radiation therapy or cancer therapies					History of psychosis Poor adaptation to stress		0		
☐ History of problems with your spleen or absence of spleen	ENDOCRINE	Yes	No		Anxiety or phobia disorder	_	_		
☐ Pregnant or planning to get pregnant?	Diabetes (requiring insulin)				mining of prioria disorder		-		

Exposure to animals outside the workplace? If yes, please describe:	Diabetes (not requiring insulin)		Panic attacks, hyperventilation		
	Childhood onset diabetes		Uncontrollable rage		
	Thyroid disease		Claustrophobia		
Occupational Concerns:	Obesity		Diagnosed personality disorder or neuroses	0	
☐ Is animal husbandry an essential part of your duties (i.e. provide food/water,	Unexplained weight loss or gain				
clean cages, groom animals, etc.)			OBSTETRIC Yes No		
☐ What % of your day are you in direct contact with animals or their blood,			Are you currently pregnant?		
tissues, fluids?					
☐ Does your work require you to use infectious agents in animals?	A. C.				
☐ Since your last exam have you experienced any of the following in relation to					
your animal exposure duties:					
☐ Sneezing and runny nose ☐ Skin eruptions including hives					
☐ Cough ☐ Chest tightness					
☐ Wheezing ☐ Shortness of breath					
	4				

MEDICAL HISTORY (Employee to complete all below)			v)	DIAGNOSTIC AND PHYSICAL FINDINGS (Examining physician to complete)				
MUSCULOSKELETAL Moderate to severe arthritis, tendonitis	Yes	No 🗆	N	Normal	Abnormal	Comments/findings:		
Amputations			1		□ Upper extremities (strength)	1		
Loss of use of arm or leg				□ notion)	☐ Upper extremities (range of			
Aseptic bone necrosis					□ Lower extremities (strength)			
Chronic back pain (back pain associated				_	□ Lower extremities (range of			
with neurological deficit)				notion)	Lower extremities (range of			
NEUROLOGICAL	Yes	No				1 2 2 2 2 2 2 2 2 2		
Any neurological disease			N	Normal	Abnormal	Comments/findings:		
Seizures			ı		☐ Cranial nerves			
Spinal cord injury			ı		□ Cerebellum			
Numbness or tingling			1		□ Motor/sensory			
Head/spine surgery			ı		□ Deep tendon reflexes			
History of head trauma with persistent def	icits				□ Mental status exam			
Chronic recurring headaches (migraine)								
Brain tumor								
Loss of memory								
Insomnia (difficulty sleeping)						TI .		

GASTROINTESTINAL	Yes	No		
Esophageal diverticula			Normal Abnormal	Comments/findings:
Severe reflux		0	□ □ Auscultation	
Hiatal hernia		0	□ □ Palpation	
Gas bloat syndrome			□ □ Organo-megaly	
Gastric outlet obstruction			□ □ Tenderness	
lleostomy obstruction			□ □ Inguinal hernia	
Diverticulitis				
Hernias				
Fistulae				
Colostomy				
Hepatitis				
Active ulcer disease	0			
Irritable bowel syndrome				
Rectal bleeding				
Vomiting blood				
GENITOURINARY	Yes	No	7 . 7	Comments/findings:
Blood in urine			Normal Abnormal	Comments initialitys.
Difficult or painful urination			□ □ Urogenital exam	
Infertility (difficulty having children)		0 0		

MEDICAL HISTORY (Employee to complete)		areases.	DIAGNOSTIC AND PHYSICAL FINDINGS (Nurse or physician to complete as					
VISION	Yes	No	HEAD A	ND NECK (Examining physician to	VISION (Nur	se to complete)		
Frequent headaches?			Complete					
Blurred vision?			Normal	Abnormal	Color Vision			
Difficulty reading?			☐ ☐ Head, face, neck (thyroid), scalp ☐ ☐ Nose/sinuses		Normal Abnormal			
Eye disease?								
Eyeglasses?				☐ Mouth/throat				
Contact lenses?			0	□ Pupils equal/reactive	Best corrected	or native vision (Sne	ellen Units)	
Radial keratotomy?				☐ Ocular motility	70.000		/	
Cataracts?				☐ Ophthalmoscopic findings	Both Fr 20/	Right Fr 20/	Left Fr 20/	
Color blindness?					Both Nr 20/	Right Nr 20/	Left Nr 20/	
			Commen	ts/findings:				
					-			

HEARING	Yes	No	2	EARS (Examining physician to complete)
Loud, constant noise or music in the				
past 14 hours?				<u>Left</u> <u>Right</u>
Loud, impact noise in the past 14 hours?				Normal Abnormal Normal Abnormal
Ringing in the ears?				□ □ Canal/external ear □ □ Canal/external ear
Difficulty hearing?				□ □ Tympanic membrane □ □ Tympanic membrane
Ear infections or cold in the past 2 weeks?				
Dizziness or balance problems?				Comments/findings:
Are you in a Hearing Conservation Program	1?□			
Do you use protective hearing equipment?				
If yes, type: □ foam □ pre-mold/plugs □	ear muf	fs		
	Yes	No		HEARING (Nurse to complete)
Have you had prior military service?				
Have you had prior ear surgery?				Audiogram: ☐ Baseline ☐ Periodic ☐ Termination (Attach current and baseline audiogram)
Have you had an eardrum rupture?				
Have you had recurrent ear infections?				Calibration Method: ☐ Oscar ☐ Biological Date
Do you wear a hearing aid?				
				Frequency 500Hz 1000Hz 2000Hz 3000Hz 4000Hz 6000Hz 8000Hz
CANCER	Yes	No		Left ear
Comments:				Right ear
		-		

	Normal	□ Abnormal	□ Explain:	
- 19				

Occupational History

(Employee to complete entire page, please indicate N/A where applicable)

Div./Br./Sec.	Duration of employment with U.S. EPA:
Description of duties:	
Exposures (dusts, fumes, vapors, gases, chemicals, radiation, noise, vibration,	on, repetitive movements, temp. extremes):
Adverse health effects possibly related to job:	
Other work performed (moonlighting, hobbies, other positions):	
Any other exposures to hazardous material? ☐ Yes ☐ No If yes, explain:	

lave you ever been off w	work for more than a day because of a	ı work-related illness or injur	y? □ Yes□ No	
yes, please specify: _				
lave you ever changed j	obs or duties due to health problems	? □ Yes □ No		
f yes, please specify:				
this is your first EPA me	edical surveillance exam, list any pre	rious jobs with associated ha	azards, starting with the one <u>before</u> your o	current position:
Agency/Company	Dates of Employment	Job Duties	Specific Hazards	

DI ELOS INDIOLES DEL OUTUBE		ir religious (per		
PLEASE INDICATE BELOW USE			DOOTO	
LEVEL A - SCBA, FULLY ENCAP				
LEVEL B - SCBA, CHEMICAL RE			AND BOOTS	
LEVEL C - AIR PURIFYING RES				
LEVEL D - COVERALLS, SAFET	Y BOOTS, GOGGLES/FACE	SHIELD, SAFETY GLASSES		
Extent of usage: Level A PPE	□ Level B PPE	□ Level C PPE	□ Level D PPE	
□ Daily □ Weekly	□ Daily □ Weekly	□ Daily □ Weekly	□ Daily □ Weekly	
☐ Monthly ☐ Rarely	□ Monthly □ Rarely	☐ Monthly ☐ Rarely	□ Monthly □ Rarely	
Additional activities/comments:		30.4 6 3.4 6.3 6.3 6.3	4.5.5.5.5.6.4	
PLEASE INDICATE LAB AND FIE	LDWORK (If 0 days, use N/	A)		
% of time in field/lab:	Fieldwork,	approximate number of days	s per year: Lab work, approximate number of day	s per year:
Environmental factors (since las	t exam):			
☐ Biological agents ☐ Solvents	☐ Hot temperatures ☐	Heavy metals ☐ Asbestos	□ Dust □ Pesticides	
☐ Fumes, smoke, gases	□ Radiation □ Excess	ive noise□ Confined space en	try □ Sewage □ Cold temperatures	
Additional factors/comments:			And the second s	

Exposure History (current position) (Employee to complete this page if applicable).

Describe your work experience during the past year or since your last exam (quarterly for those with frequent exposures [e.g., OSCs]) at EPA work sites where enrollment in medical surveillance may be required (e.g., where there were exposure sources such as oil, biohazards, ionizing and non-ionizing radiation, semi-volatile organic compounds/volatile organic compounds, lead, mercury, other heavy metals, asbestos, pesticides, PCB/dioxins, excessive heat/cold, vibration, repetitive movements, or prolonged exposure to noise above 80dB). Each SHEMP manager will select whether the table or the narrative should be used. [OSCs must be prompted to fill out the table quarterly in the workflow.]

Site (name; location; ID; entry into restricted, hot or exclusion zones)	Dates (Presen t on- site)	Exposure Sources (chemical, physical, biological, ergonomic)	Exposure (# of days, hrs per day, concentrations, if known)	Level(s) of PPE (A,B,C,D	EPA TLD (dosimeter worn?)	Symptoms from Exposure	Job Duties
					□ Yes		
					□ Yes		
					□ Yes		
					☐ Yes		
					☐ Yes		
					☐ Yes		

Narrative
If during the time since your last exam you worked at a job site where there were exposure sources. Please provide details if known, such as location, duration of work, exposure sources (e.g., chemical, physical, biological, ergonomic), and the exposure (i.e., # of days, hrs per day, concentrations/description of amount), below. Those with frequent exposures should update this section often:

Examining physician, please check all the topics you discussed during the diagnostic work-up/physical examination	WORKPLACE EXPOSURE MONITORING (Examining physician to complete)	SUMMARY OR ABNORMAL FINDINGS SUMMARY WITH PLAN OF ACTION (Examining physician to complete)
□ Diet	Is workplace monitoring data or other exposure	
□ Low-calorie	data for this employee or this position available for	
☐ Low-fat	review?	_
□ Low-salt	□ Yes □ No	
☐ Cholesterol		
☐ Hypertension	If yes, what type of data are available?	-
□ Exercise	in you, multippe of data allo aramado.	
☐ Obesity		
☐ Smoking cessation		_
☐ Respirator use		
☐ Avoid sun exposure/sun screen	Acute Exposure Data	
☐ Alcohol use	☐ Workplace monitoring data	
☐ Cancer screening	☐ Individual dosimetry data	
☐ Immunizations	□SDS	_
☐ Hearing protection		
☐ Vision referral		

☐ Other personal protective equipment	Periodic Exposure Data	
☐ Job stressors	☐ Workplace monitoring data	The employee has been medically examined by me under the
☐ Referral(s)	☐ Individual dosimetry data	provisions of the EPA National Occupational Medical Surveillance Program and has been advised of the examination findings.
☐ Others:	□SDS	Program and has been advised of the examination inidings.
	_	
	How were data made available?	To the RMO: Based on the following indicated requirements for
	☐ Electronic database	this individual:
	☐ Hard copy report	☐ A prescription for antibiotics ☐was ☐was MOT written and signed
	☐ Employee self-report	by the examining physician and given to the Employee/Safety
	☐ Page 8 of the medical exam form	Manager.
		☐ Employee ☐has ☐has NOT been cleared for the Voluntary
	Please explain what changes, if any, were made in the examination due to review of these data:	Exercise Program
		Comments if box was checked for "was/has NOT":
	Based on your knowledge of the physical demands	
	of the position and/or the potential exposure to occupational hazards, does the Employee need to continue in a medical surveillance program?	
	□Yes	-
	□No	
	☐ Cannot determine based on information available	
	☐ Other:	Note: Please do not provide any official statement (oral or written) concerning the examinee's fitness or capability to
		perform the duties of any occupation. The Reviewing

	Г	Madical Officer (DMO) will provide written eninione to the
		Medical Officer (RMO) will provide written opinions to the agency.
		ugonoy.
SIGNAT	RES	DATE PHYSICAL COMPLETED
have had the examination findings explained to me and receive	a copy of the examination if requested. I understand the medical r	
Client		
Nurse		
Examining Physician		

PAGE 10 – Employee Notification Statement

(Examining Physician to complete entire page)

U.S. ENVIRONMENTAL PROTECTION AGENCY IPLOYEE NOTIFICATION FROM EXAMINING PHYSICIAN STATEMENT

	EMPLOYEE NOTIFICATION FROM EXAMINING PHYSICIAN STATEMENT
	The employee is encouraged to review the lab results with his/her treating physician.
	The employee has been advised of any medical condition(s), occupational or nonoccupational, which dictates further medical examination or atment.
	The employee has been informed by the physician of the increased risk of lung cancer attributable to the combined effect of smoking and bestos exposure.
	With respect to Beryllium the employee has been advised by the PLHCP conducting the examination of the risks and benefits of participating in the medical surveillance program and the employee's right to opt out of any or all parts of the medical examination.
	The physician has clearly and carefully explained to the employee the results of the medical examination, including all biological monitoring results and any medical conditions related to cadmium exposure that require further evaluation or treatment, and any limitation on the employee's diet or use of medications.
	The employee has been informed by the physician of any medical conditions which would be aggravated by exposure to formaldehyde, whether these conditions may have resulted from past formaldehyde exposure or from exposure in an emergency, and whether there is a need for further examination or treatment.
	The employee has been informed by the Physician or other Licensed Health Care Professional (PLHCP) that Methylene Chloride (MC) is a potential occupational carcinogen, of risk factors for heart disease, and the potential for exacerbation of underlying heart disease by exposure to MC via its metabolism to carbon monoxide.
	With respect to silica the employee should be examined by a specialist (pursuant to paragraph (i)(7) of the 29 CFR 1910.1053 general Industry Standard; or, to paragraph (h)(7) of the 29 CFR 1926.1153 construction standard) if the chest X-ray provided in accordance with this section is classified as 1/0 or higher by the B Reader, or if referral to a specialist is otherwise deemed appropriate by the PLHCP.
	The employee has been informed by the physician of the results of the medical examination and any medical conditions resulting from [see below] exposure which require further explanation or treatment.
	□ Acrylonitrile □ Arsenic □ Asbestos □ Benzene □ 1,3 Butadiene □ Ethylene Oxide □ Lead □ Methylenedianiline □ Methylene chloride
Ex	camining Physician's Printed Name
Ex	camining Physician's Signature:

Date Completed:			-
PAGE 11 - SHEMP Manager In	put		(SHEMP Manager to complete entire page and check appropriate boxes)
that may have adverse health effects; and a characterization ubstantiating Comments / SHEMP manager descriptions.	on of phys otion of r	ically dema need/expo	
Biological Monitoring: Blood Lead Urine Hea	avy Metal	s Seri	um PCB's Lyme Disease Titers Other (describe):
Occupation	Freque	ncy (years)	Enrollment Criteria:
Emergency Response & On-Scene Coordinator		1	☐ Position descriptions, regularly assigned tasks, & duties involve emergency response activities with the potential for
Diver (HazMat/non-hazmat)		1/2	exposure to occupational hazards (e.g., chemical agents, radiological agents, biological agents) and/or physical stressors.
Post Event	Ep	isodic	☐ Enrollment is based on activities and potential or known exposures that are currently regulated by OSHA (and the
Not listed below		4	applicable regulation mandates medical surveillance).
	A STATE OF THE PARTY OF	al Exposure	☐ Position descriptions and regularly assigned tasks and duties present the potential for exposure to chemical, radiological,
	< 30 days	≥ 30 days	or biological agents, or physical stressors at or above the Agency-established MSAL.
Animal Handler	uays	uays	□ Position descriptions and regularly assigned tasks and duties require the use of respiratory protection due to potential
Clean Air Inspector/Enforcement Officer			exposures at or above the MSAL or reasonably significant occupational exposures that may have adverse health effects.
Federal Insecticide Fungicide & Rodenticide Enforcement			☐ The position description and regularly assigned tasks and duties involve routine physically demanding, rigorous work.
fficer	4		D 14 III DD 14 DVI - DC
Field Sampling Employee			Respirator Use: Required Voluntary Emergency/escape only Not required Type(s) of Respirator: SCBA Cartridge Full Cartridge Half N95 PAPR Airline
☐ National Emission Standard for Hazardous Air Pollutants			Protective Gear: □ Level A □ Level B □ Level C □ Level D
Asbestos Hazard Emergency Response (Annual exams – general			Level of Effort: ☐ Heavy ☐ Moderate ☐ Light
nazaro Emergency Response (Annuai exams – general ndustry)	323	1 2	Temperature and Humidity extremes possible: ☐ Yes ☐ No
National Pollutant Discharge Elimination System Inspector	2 🗖	1 🗆	SHEM comments on respirator use:
Pesticide Laboratory Employee/ CWA Lab Employee			Detected West Assistance to D Administrative D Laboratory D Field
Radiation Employee			Potential Work Assignments: ☐ Administrative ☐ Laboratory ☐ Field Deployment/Travel: ☐ Local ☐ National ☐ International
Remedial Project Officer/Manager			Deployment fravel. Disolat Difficultational Difficultational
Resources Conservation & Recovery Enforcement Officer			Special Programs: ☐ MCM ☐ Duodote ☐ Voluntary Exercise Program
☐ Toxic Substances Control Enforcement Officer			CONTRACTOR
Underground Storage Tank Inspector		11600	
Wetlands Employee	7		
T Laboratows Employee	ΔП	2 🗖	1

	Past years	Exposure level/Content %	≥ 10 days	≥ 15 days	≥ 30 days	≥ 60 days
☐ 13 carcinogens		1				
☐ 1,2 dibromo-3-chloropropane	Jan	1				
☐ 1,3 Butadiene	May be applicable	1, then 3	1, then 3		1, then 3	1, then 3
☐ Acrylonitrile	A	1				
☐ Asbestos construction					1	
☐ Asbestos general industry		1				
☐ Benzene	May be applicable		1		1	
☐ Beryllium	May be applicable				1, then 2	
☐ Cadmium	May be applicable				1, then 2	
☐ Chromium VI					1	
☐ Coke oven emissions			- 1		1	
☐ Ethylene oxide	May be applicable	AT A THE			1	
☐ Formaldehyde		1				
☐ Inorganic arsenic	May be applicable				1	
☐ Lead	May be applicable		- 1		baseline	
■ Methylenedianiline				1 (skin)	1	
☐ Methylene chloride		1, then 3 sometimes	1, then 3	1, then 3	1, then 3	
				1 yr if ≥ 45 yrs old		
☐ Silica general industry & construction					1, then 3	
☐ Vinyl chloride		1				*

U.S. ENVIRONMENTAL PROTECTION AG	ENCY MEDICAL SURVEILLANCE CLEARANCE STATEMENT	TYPE OF EXAM
(Nurse to complete) Name of Client:	(Nurse to complete) Health Center Site Code: Complete Mailing Address:	(Nurse to complete) □ BASELINE □ PERIODIC
Date Exam Completed:		□ EPISODIC □ EXIT
Organization/Facility Designator:	Health Center Phone and Fax:	(Nurse to complete)
Supervisor Name:	SHEMP Manager Name:	□ Animal Handler

	Complete Mailing Address:	☐ Clean Air Inspector/
Supervisor Phone:		Enforcement Officer
		☐ Diver (Non-Hazmat)
	edical Review Officer only and input from SHEMP Manager]	☐ Hazmat Diver
The above-named EPA employee has been medically examined under the provisions of the EPA Nati- the Examining Physician.	onal Occupational Medical Surveillance Program and has been advised of the examination findings by	☐ Emergency Response and
☐ I have reviewed the Employee medical, occupational, and exposure histories; physical examination	n findings; and diagnostic tests.	On-Scene Coordinator
In my opinion, this employee:		
☐ Is medically qualified to wear the indicated levels of PPE:		☐ Federal Insecticide
☐ Level A ☐ Level B ☐ Level C ☐ Level D (Respirator use is no	t required)	Fungicide & Rodenticide
□ Is medically qualified to wear the indicated respiratory equipment: □ APR respirator □ PAPR respirator □ SCBA respirator □ Air-line respirator □ SC	CLIBA respirator	Enforcement Officer
	is a supplication	(FIFRA)
☐ Is medically qualified to participate in EPA office, laboratory and field activities, as required for the	pir position.	☐ Field Sampling Employee
☐ Is medically qualified for all EPA diving-related duties and use of breathing apparatus.		□ Lab Employee
☐ Is medically cleared for issuance of DuoDote injector, if applicable.		Lab Employee
$\ \square$ The employee was evaluated for MCM antibiotic prescription use and a prescription for antibiotic	s was provided to the employee.	□ National Emission
☐ Is cleared for the Voluntary Exercise Program, if applicable.		Standard
□ Is qualified to participate in EPA office, field and/or laboratory activities with the following recomm	nendations:	for Hazardous Air Pollutants
☐ HEARING - Supervisors should be aware that the employee demonstrated some hearing to is not feasible, supervisors should ensure that appropriate hearing protective equipment is worth	ss. The employee should avoid, whenever feasible, all hazardous noise exposures. When avoidance n.	(NESHAPS)/ Asbestos
☐ VISION - Supervisors should be aware when making duty assignments that the employee h documents the impairment has been corrected.		Hazard Emergency Response
$\hfill \square$ EXERTION/STRESS - Supervisors should be aware that the employee may be at risk if	required to perform heavy work or work under extreme environmental conditions.	·
□ FIELD ACTVITIES – Supervisors should be aware that the employee may be conditions.	at risk if required to perform heavy work or work under extreme environmental	(AHERA)
□ RESTRICTIONS:		□ National Pollutant Discharge
☐ Is not medically qualified at this time for this position.		Elimination System
☐ A medical recommendation cannot be made at this time. Further medical evaluation, as describe	d below or on the attached page, is needed.	Inspector (NPDES)
The following occupationally-related medical findings were noted during this evaluation:		☐ Pesticide Laboratory

My recommendations, if any, include:		Employee/CWA Lab
		Employee
SHEMP Manager Frequency: □ One Year □ Two Years □ Three Years □ Four Years □ Episodic □	Exit exam (no further exams will be scheduled)	□ Radiation Employee
Medical Review Officer clearance: ☐ One Year ☐ Two Years ☐ Three Years ☐ Four Years ☐ Episodic ☐ Exemples: ☐ Comments: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	kit exam (no further exams will be scheduled) □ Other Contact:	□ Remedial Project Manager
		☐ Resources Conservation &
Note: Employees are advised to review any abnormal lab results with their primary	care physician, when appropriate.	Recovery Enforcement
		Officer (RCRA)
		□ Toxic Substances Control
		Enforcement Officer
Reviewing Physician's Signature:	Date Medical Review Completed:	(TSCA)
Reviewing Physician's Printed Name:	-	☐ Underground Storage Tank
		Inspector (U.S.T.)
		□ Wetlands Employee

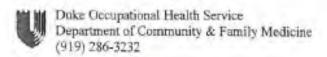
Form for both SoBran and MPF Federal Contract Employees



Box 3834 Duke University Medical Center Durham, North Carolina 27710

	COMPREHENS	IVE HEALTH	HISTORY	
GENERAL INFORMATION	I:		Date:	
lame:				Marital Status:
Address:				☐ Single
Birth date:		Sex:	Race	
lobbies/Interests:				Divorced
PERSONAL HEALTH HIST	TORY:			☐ Widowed
Do you have any medica No Yes				
2. Have you ever been hosp □ No □ Yes	oitalized or had any oper (please explain):	rations:		
3 Have you ever had any s	erious illnesses or injuri (piease explain):	ies not described above?		
Have you ever had any s No Yes Do you have any allergi No Yes	(please explain):es to medications or othe	er substances (including	non-prescription	medications, like aspirin
□ No □ Yes Do you have any allergi □ No □ Yes	(please explain):es to medications or other (please explain):	er substances (including	non-prescription	
□ No □ Yes Do you have any allergi □ No □ Yes 5. Do you take medicines □ No □ Yes 6. When was your last teta	(please explain):es to medications or other (please explain):es of any kind? (please list medications	er substances (including	non-prescription	
□ No □ Yes Do you have any allergi □ No □ Yes 5. Do you take medicines	(please explain):es to medications or other (please explain):es of any kind? (please list medications	er substances (including	non-prescription	

	Has any blood relative in y	Y	N	4
High blood pressure				
Heart attack or heart d	isease			
Diabetes ("sugar")				
Tuberculosis				
Asthma or allergies				
Cancer or leukemia				
Thyroid problems				
Carpal tunnel syndron	ne e			
Sickle cell amemia or t				
Alcoholism or drug at				
Psychological problen				
Mental illness				
Disability from pain p	roblems			
Do any other diseases				List:
If yes, how n When did yo On the average, l Beer:	how much alcohol do you drink eac cans/bottles Wine:	ch week?	For	Liquor: drinks If yes, what kind and how often?
S. Do you get regul	at belts? never or rarely lar stremuous exercise outside of your times/week what kind of exercise	urjob?	nev	er or rarely 1-2 times/week
6. FOR WOMEN: FOR MEN:	Date of last Pap smear (month/	year):		
	Do you do breast self-examinal Do you examine your testicles		nonth?	□ No □ Yes □ No □ Yes
7. Do you see a der	Do you examine your testicles		nonth?	The second secon
	Do you examine your testicles	each monti	nonth?	The second secon
8. Do you have you	Do you examine your testicles ntist regularly? No ur blood pressure checked regularly	each monti	nonth?	□ No □ Yes
Do you have you Do you examine Have you had a	Do you examine your testicles ntist regularly?	each monti	nonth? i? No	□ No □ Yes □ Yes □ Yes
9. Do you examine 10. Have you had a 11. Have you ever h	Do you examine your testicles ntist regularly?	each monti	nonth? i? No	□ No □ Yes □ Yes



Box 3834 Duke University Medical Center Durham, North Carolina 27710

OCC	CUPATION	AL R	ECC	RD					
Name:									
INITIAL VISIT				SUBS	EQUE	NT VIS	SITS		
DATE:				1 3	11			1	2.1
Company:		11	11		11	11	-16		H
Job Title: Description of activities:									
				- 16					1
		Job Title: Job changes:		lob Title; lob changes:		Job Title: Job changes:		Job Tide. Tob changes:	
List below as completely as possible all of the materials, chemicals, or substances with which you work:		ABOVE: Note any changes in your job activities since your last visit. BELOW: Check whether you still work with the materials, chemicals, or substances which you have previously listed. Add to the bottom of the list any new substances used since your last visit.							
	Date Started	Yes	No	Yes	No.	Yes	190	Yes	-Ivo
									7500
				3				212	1
	-								
				3					

continue on the next page

Appendix 6: Personnel Medical Evaluation Form

INITIAL VISIT		SUBSEQUENT VISITS								
	D	ATE:				1			4	
Do you work with or have significant exposure to any of the			Since your last visit, have you worked with any of the following?							
following?	Yes	No	Yes	No	Yes	No	Yes	No	YES	No
Vapors or gasses					7	1		1		
Dusts				- 11	4	15			100	18
Fumes or mists			1		16.	1 -				
Metals					100	0				53
Biologic agents					-	E. F.			6-3	1
Infectious agents						PE		110	1	
Laboratory animals					1					100
Loud noises			1			10.4			1	
Extreme heat or cold			11			The same				1
Vibration					2	700		1		
Radiation									iros l	
Stress which causes problems or symptoms at work or at home					-				000	6.5
Hazardous weste										350
Unusually demanding hand or arm duties or postures					13.0					
										7
						300			-	
		-				-	1		-	
		-	-			1	-		-	
	-	-	-	-	200		-		-	
	-				-	-	-		700	
	-	-	-	-	-	-	-	-	-	
		-	-	-	150		-	-		
			Since your last visit, have you?							
Have you ever:	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Filed a weeker's compensation claim or received benefits for an occupational accident, injury, or illness?					13	T				F
Been disabled or restricted for medical reasons?						T				
Changed jobs for health or safety reasons?			1		100	15				100
Had difficulty wearing a respirator?						1/3			100	1
Do you live near a plant, factory, dumpsite, or other potential source of pollution?		П			1					
Do you have any hobbies (such as painting, gardening, welding, woodworking, handressing, or scaba diving) which involve exposure to chemicals or physical hazards?										
Are there any substances in or around your home that might be harmful (fumes, gases, inculation, pesticades, paints, or others)?						1				
Do you have more than one job?	-	-	-	-	-	-	-	-	-	-
		-	1	1		1	1		1	1
										I
On the average, how many hours per week do you work?					-			1	1	

Appendix 6: Personnel Medical Evaluation Form

Duke Occupational Health Services

Components of the OHS Panel and Urinalysis

OHS	DI	and	Dow	Low
Ons	D	000	ran	ıeı

Glucose, serum BUN (Blood Urea Nitrogen)

Creatinine, serum

Bilirubin, Total

Alkaline Phosphatase, S

AST (SGOT)

eGFR (nonAfrican Am and African Am) estimated Glomerula Filtration

GGT

ALT (SGPT)

Triglycerides

LDL Cholesterol

HDL Cholesterol

VLDL Cholesterol

Cholesterol, Total

WBC

RBC

Hemoglobin

Hematocrit

MCV

MCH

MCHC

RDW

Neutrophils

Platelets

Lymphs

Monocytes

Eos

Basos

Neutrophils (Absolute)

Monocytes (Absolute)

Eos (Absolute)

Baso (Absolute)

Immature Granulocytes

Baso (Absolute)

Immature Grans (Absolute)

Urinalysis

Specific gravity

pH

Urine-color

Appearance

WBC Esterase

Protein

Glucose

Ketones

Occult Blood

Bilirubin

Urobilinogen, Semi-Qn

Nitrite, urine

Microscopic Examination

WBC

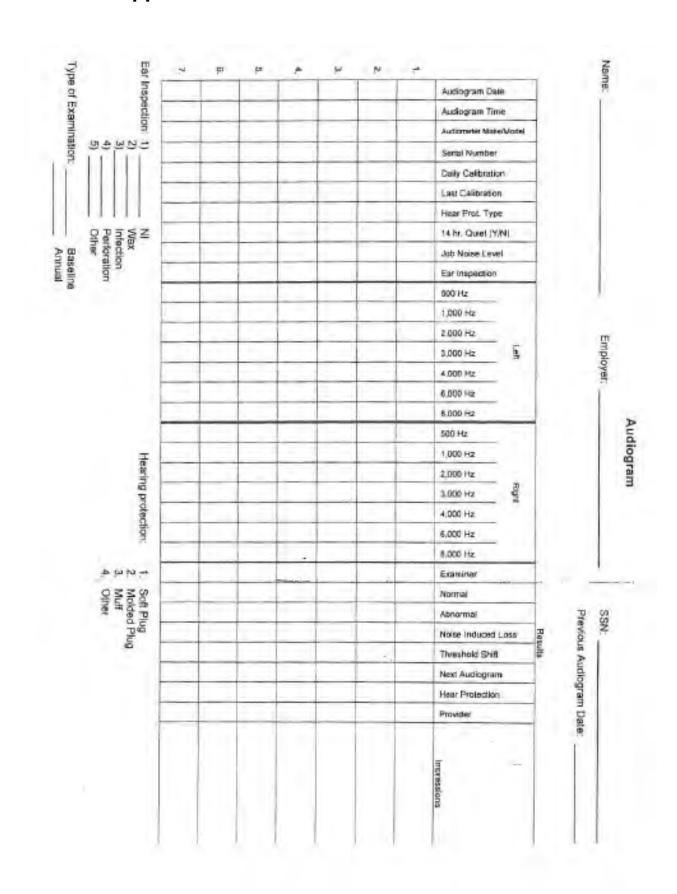
RBC

Epithelial Cells

Mucus Threads

Bacteria

Appendix 6: Personnel Medical Evaluation Form



Appendix 7: IACUC/OB Membership Roster

Please provide a Committee roster, indicating names, degrees, membership role, and affiliation (e.g., Department/Division).

NAME	Degrees	Membership Role	Affiliation
Dr. Michael Narotsky	PhD Research Toxicologist	Chair	ORD/CPHEA/PHITD/NETB
Exemption 6	MA, CPIA	IACUC Member	Director, Animal Resources Program Office ORD/ORM/RSCD/FRCB
Dr. Leslie Jarrell	JD, DVM, DACLAM	Attending Veterinarian	SoBran, Contractor for the US EPA
Exemption 6 Exemption 6	PhD Toxicologist	IACUC Member	ORD/CPHEA/PHITD/NETB
Exemption 6	MS, Biologist	IACUC Member	ORD/CCTE/BCTD/AETMB
Exemption 6 Research Biologist	PhD DABT	IACUC Member	ORD/CPHEA/PHITD/CIB
Exemption 6	M.S., Software Developer	Non-Affiliated Member	No affiliation
Exemption 6	MPA, REHS	IACUC Member SHEM* representative	ORD/ORM/RSCD/IOI
Exemption 6	LATg	Ad Hoc	Alpha-Omega BioServices, Inc
Exemption 6	PhD	Ad Hoc Statistician	contemplating retirement
Exemption 6	DVM, DACLAM	Alternate Veterinarian	SoBran, Contractor for the US EPA
Exemption 6	Industrial Hygienist	Alternate IACUC Member SHEM* representative	ORD/ORM/RSCD

Please provide the latest two Minutes of the IACUC/OB meetings.

The RTPP has two types of IACUC meetings: Quarterly Business Meetings and IACUC Protocol Review Meetings, though there is some overlap of topics discussed. Attached are the Minutes from the last of each of these meetings. The September Quarterly Business Meeting Minutes are in draft form; these Minutes will be reviewed and approved by the IACUC at the December Quarterly Business Meeting.

IACUC Quarterly Business Meeting (QBM) 09/18/2019

In Attendance:

Mike Narotsky (Chair), Leslie Jarrell (Attending Veterinarian), Exemption 6 (Director, Animal Resources Program Office) (ISTD Representative), Exemption 6 (ISTD Representative), Exemption 6 (IACUC Administrator), Exemption 6 (Via Phone-nonaffiliated) and Exemption 6 (Facility Manager). A quorum was maintained at all times.

Minutes prepared by Exemption 6

Quarterly Business Meeting was called to order at 1:05pm by Chair Mike Narotsky.

- A. Review/Approval June 13, 2019 IACUC Quarterly Meeting Minutes
 - a. These minutes were not ready therefore not approved
- B. Subcommittee and Other Reports/Updates
 - a. Training (Jarrell)
 - i. 29 classes since April 2019
 - ii. 4 Step process to be approved and ready to place on protocols
 - b. PAMs Exemption 6 report
 - i. 2 PAM completed since June 2019
- C. Old Business

a. Biosecurity and Visitor Form Exemption 6

- i. New Vivarium Access form has been created and placed on the IACUC website
- ii. The Vivarium Access form has been sent to all Vivarium users via email
- iii. The Biosecurity signs have been changed and installed in all airlocks

b. Rabbit updates (Jarrell)

- i. Had a rabbit handling class with Klinefelter's lab
- ii. The student still needs work and PI realizes her needs to be supervised
- iii. Podo-dermitis is still present (mild)
- iv. Exercise pen log sheets are now being used
- v. May change to a sheet per rabbit
- vi. These logs will become medical records

c. Adoption Policy (Jarrell)

- i. Sent to the EPA Legal team.
- ii. Still Waiting on a response
- iii. There has been a Congressional Inquiry about Adoption Policy
- iv. We are still "retiring in place"

D. New Business

a. Control Animals

- i. Look into possible carcass donations to zoo or raptor facility
- ii. Will check to see what other institutions donate

b. Policy (Jarrell)

i. Create a policy for retire in place

c. Sentinel Program (Jarrell)

- i. Would like to change this program
- ii. Will check feces via PCR instead of Vendor surveys,
- iii. Would like to extend program to 6 months, currently is was every 3 months.

d. Review of Adverse Events in the last 6 months

- i. Exemption 6 2 animals died (300 dose)
- ii Exemption 6 1 animal
- iii. Exemption 6 small pups

e. Animal Room Temperature

- i. Temperatures comply with the guide
- ii. Can the room temps be increased?
- iii. Get a list of room that have the ability to increase temp

f. Cage Card Holders

i. Will send out an email to all users to remind them to not remove the original cage card.

g. Exemption 6 cages update

- i. New cages have been put together
- ii. Steel pans have been installed

h. ACUP Forms

- i. Mike Narotsky had sent out an email about the Protocol Template and the Amendment Template
- ii. Going thru each document, page by page

2:06pm Exemption 6 leaves meeting. Quorum Maintained.

Work on ACUP Template on the computer

2:41pm Exemption 6 leaves meeting. Quorum Maintained.

Still working on the computer

3:18p, Exemption 6 leaves meeting. Quorum Maintained.

3:28pm Exemption 6 steps out of meeting. Quorum Maintained.

3:31pm Exemption 6 returns to meeting. Quorum Maintained.

Finished with ACUP Protocol

Finished with ACUP Amendment

Mike Narotsky will send out an email to all animal users about information about the Vivarium.

He will attach the Vivarium Access form.

Exemption 6 will send Mike Narotsky an updated Vivarium email list.

Meeting adjourned at 3:54pm

IACUC Review Meeting: 09/25/2019

In attendance: Leslie Jarrell, Mike Narotsky, Exemption 6Exemption 6Exemption 6Exemption 6Exemption 6Exemption 6



Meeting was called to order by Mike Narotsky at 1:06 PM.

1:12pm Exemption 6 enters the meeting. Quorum maintained

Meeting minutes were approved from 08/28/2019.

New Business:

- 1. Mike Narotsky will email the Animal User community about following Updates
 - a. Deadlines for submission to the IACUC
 - b. Direct to DMR
 - c. Category C Lab personnel
 - d. Keep original cage card
 - e. Technical Service Requests

Old Business:

- 1. Exemption 6 Study
 - a. Finding Adverse effects at the High dose
 - b. Would like to dose at 130 mg/kg
- 2. Exemption 6 Study
 - a. New caging is working
 - b. Rats are getting exercise
 - c. Would like to purchase running wheels for caging but they are out of stock from the vendor

Agenda:

Items: 1

Item 1:

22-08-003 Amendment 1: The IACUC reviewed this document and unanimously voted to send to DMR – waive 3 Day waiting period-following FCR. DRs: Mike Narotsky and Leslie Jarrell. Discussion was as follow:

Make Administrative changes to the following:

1. Euthanasia Schedule

2. Gentle handling

Meeting adjourned at 1:38pm.

Please attach a <i>blank</i> copy of form(s) used by the IACUC/OB to review and approve studies. Include forms used for other periodic) renewal, modifications, amendments, etc., as applicable.	or annual (or
New ACUP Form	
Section BI - Base Info	
1. Is this ACUP associated with Research Project? [Yes / No]	
1.1. Research Project	
2. ACUP Name Please include the species and avoid abbreviations.	
3. Is there a previous ACUP/LAPR? [Yes / No]	

3.1. Previous ACUP/LAPR

Section PD - Project Description

1. Research Project Description Explain the study objective(s) in non-technical language such that it is understandable by non-scientific persons. Spell out all acronyms and abbreviations with their initial use.	
2. Benefits of Proposed Research Explain how the benefits from the knowledge gained from this research outweigh the costs to the animals used in this research. Does this benefit the species that will be used?	
3. Research Project Approach Describe the experimental design that will be used to meet the project objectives.	

Explain how it	e that Study is Not Unnecessary Duplication t was determined that this is not unnecessary duplication. For novel work, a summary of literature search (includin keywords, years covered) would be helpful. If this is a repetition of prior work, explain why this work is necessary
-	e continuation of the study s required if this protocol is related to a previously activated animal protocol.
6. Why is the	Rationale for Proposed Animal Use e use of animals necessary his cannot be accomplished with a computer or other experiments.

7. Justify the species requested	
Section TM - Team Members	
The team must comprise one active Principal Investigator and Alternate Contact to be complete. If team member does not appear in member to the team.	n the menu, please add the new team
Name	
Organization	
Role	

Section PRD - In Vivo Procedures

1. Experimental Design Description

NHEERL Training

[Yes / No]

Provide the big picture for the study design here. The IACUC is looking to understand what will happen to the animals "cradle to grave". Describe cohorts, age/weight and sex of animals, the rationale and organization of proposed treatments and exposures, timelines and similar design items. Specific descriptions of procedures and justifications for animal numbers belong in different sections.

2. Number of Animals Justification
Does this ACUP include any of the following
3. Restraint (> 15 min)
Describe how animals will be monitored, how health status will be tracked, and what records will be maintained. [Yes / No]
3.1. Describe how animals will be monitored, how health status will be tracked, and what records will be maintained.

4. Food and/or water restriction (>6 hrs) Describe how animals will be monitored, how health status will be tracked, and what records will be maintained.
[Yes / No]
4.1. Describe how animals will be monitored, how health status will be tracked, and what records will be maintained.
5. Survival surgery Any surgery followed by deliberately allowing the animal to wake up. How long they survive after waking does not matter.
[Yes / No]
5.1. Provide scientific justification for survival surgery

6. Non-survival surgery

Any surgical procedure where the animal is euthanized prior to waking. Terminal surgeries include procedures where the animal is alive only to allow organ function to make a procedure possible. Examples would be liver perfusion to collect hepatocytes or thoracotomy and subsequent blood collection from cardiac or aortic puncture.

[Yes / No]

Animal Pain/Distress Categories

7. Category B Adult

Animals being bred, acclimatized, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. Non-invasive observation only of animals in the wild.

7. Category B Offspring

Animals being bred, acclimatized, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. Non-invasive observation only of animals in the wild.

8. Category C Adult

Animals that are subject to procedures that cause no pain or distress, or only momentary or slight pain or distress and do not require the use of pain-relieving drugs. Examples might be weighing an animal, or delivering an injection of a non-irritating substance.

8. Category C Offspring

Animals that are subject to procedures that cause no pain or distress, or only momentary or slight pain or distress and do not require the use of pain-relieving drugs. Examples might be weighing an animal, or delivering an injection of a non-irritating substance.

9. Category D Adult

Animals subjected to potentially painful or stressful procedures for which they receive appropriate anesthetics, analgesics and/or tranquilizer drugs. An example would be survival surgery performed under anesthesia. Category D procedures require scientific justification and a search for alternatives.

9. Category D Offspring

Animals subjected to potentially painful or stressful procedures for which they receive appropriate anesthetics, analgesics and/or tranquilizer drugs. An example would be survival surgery performed under anesthesia. Category D procedures require scientific justification and a search for alternatives.

10. Category E Adult

Animals subjected to potentially painful or stressful procedures that are not relieved with anesthetics, analgesics and/or tranquilizer drugs. Examples might include exposing animals to levels of pollutants which cause irritation of the eyes or respiratory tract; immobilization or paralysis of a conscious animal; application of noxious stimuli such as electrical shock that the animal cannot avoid/escape; continued research after clinical symptoms are evident without medical relief or requiring euthanasia. Category E procedures require scientific justification, including a justification for not using analgesics, anesthetics, etc., and a search for alternatives.

10. Category E Offspring

Animals subjected to potentially painful or stressful procedures that are not relieved with anesthetics, analgesics and/or tranquilizer drugs. Examples might include exposing animals to levels of pollutants which cause irritation of the eyes or respiratory tract; immobilization or paralysis of a conscious animal; application of noxious stimuli such as electrical shock

that the animal cannot avoid/escape; continued research after clinical symptoms are evident without medical relief or requiring euthanasia. Category E procedures require scientific justification, including a justification for not using analysesics, anesthetics, etc., and a search for alternatives.
Does this protocol include any of the following procedures?
12. Category C Procedures
[Yes / No]
13. Non-Surgical Category D&E Procedures
[Yes / No]
14. Surgical Category D&E Procedures
[Yes / No]
12. Category C Procedures
12.1. Treatments
List dosages, duration of exposure, route, volume, and frequency.

12.2. Survival Blood Collection List method, volume, and frequency.
12.3. Terminal Blood Collection
12.4. Testing Methods Include non-stressful dietary restrictions/modifications, mild non-damaging electric shock.

12.5. Animal restraint and confinement beyond routine housing and handling. Include a description of the type of restraint device, acclimation to device, duration of restraint.
12.6. Breeding for experimental purposes Information can include length of pairing, number of generations, etc.
12.7. Describe how animals will be identified and monitored Include description of identification procedures. (For example, if transponders are used, how are the animals prepared?) Include frequency of observations and by whom.

13. Non-Surgical Category D&E Procedures

13.1. Treatments

List dosages, duration of exposure, route, volume, and frequency.

Appendix 9: IACUC/OB Protocol Form 13.2. Blood Collection Provide a description of the procedure including method, volume, and frequency if appropriate. Indicate if the procedure is survival or terminal. Include preparatory methods, descriptions of incisions, etc. 13.3. Testing Methods Include non-stressful dietary restrictions/modifications, mild non-damaging electric shock.

13.4. Restrictions placed on the animals basics needs

Information can include food and/or water restriction, light cycles, and temperature. Provide details regarding the length of restriction. Describe the method(s) for assessing the health and well-being of the animals during restriction. (Amount of food or fluid earned during testing and amount freely given must be recorded and assessed to assure proper nutrition.

13.5. Describe how animals will be monitored
12.6 4 1 1
13.6. Analgesia List drugs, dosages, route of administration and frequency
13.7. Are treatment related deaths expected?
[Yes / No]
13.7.1. Justify treatment deaths

14. Surgical Category D&E Procedures
14.1. Surgical Procedure Description
Include presurgical preparation, aseptic technique, surgical closure, etc.
14.2. Anesthetic Regimen
Include drugs, dosages, volume, route of administration and delivery schedule. The use of paralytic or neuromuscular blocking
agents without anesthesia is prohibited.

14.3. Postoperative Care

Include thermal support, special feeding, responsible personnel, removal of sutures/staples, frequency and duration of monitoring including weekend and holiday care.

14.4. Post Operative Analgesics	
Include drugs, dosage, and volume and route of administration, and frequency.	
14.5. Will any animal be subject to more than one surgical procedure over the course of it location?	s lifetime, at any
[Yes / No]	
14.5.1. Provide rationale: Multiple surgical procedures, major or minor, must be scientific	cally justified
2 noise 2 contract relativities surgicus procedures, major or minor, must be scientific	Justicu.

15. Humane Interventions
5.1. Resultant effects
Do the investigators expect to see following procedures or treatment? Please include transitory as well as permanent effects. Examples might include lethargy, ataxia, salivation or tremors. Indicate the expected duration of these effects.
5.2. State the criteria for determining temporary or permanent removal of animals from the study Describe actions to be taken in the event of deleterious effects from procedures or chemical exposures. Describe actions to be taken in the event of clinical health problems not caused by procedures or exposures.

16.1. Provide narrative regarding the sources consulted to ascertain whether acceptable alternatives exist for potentially painful/distressful procedures. Include databases searched or other sources consulted, the date of the search and years covered by the search, and key words and/or search strategy used. Assistance with searches is available through the EPA Library Staff.
Section REQ - Animal Requirements
1. Animals to be purchased from a Vendor for this study
2. Animals to be transferred from another ACUP
2.1. ACUP that is the source of the transfer
3. Offspring produced onside (used for data collection and/or weaned)

Total Number of animals for duration of the ACUP
4. Species (limited to one per ACUP)
5. Strain(s)
6. Describe special requirements for animals with altered physiological responses
7. Sources of Animals
7.1. Describe your Animal Source

8. Will any animals be housed in areas other than the animal facility longer than 12 hrs
[Yes / No]
9.1. Catallita Facilita
8.1. Satellite Facility
8.2. Room Numbers
9. Housing or Husbandry Requirements/Housing and Enrichment
10. Special Assistance Requested

Please describe any Technical Service Requests which may be submitted to the Animal Resources Program Office to obtain Animal Care Staff assistance with animal procedures. Technical Service Requests can be submitted for such diverse assistance as assisting with oral lavage dosing or vaginal lavage, assistance transporting animals to or from High Bay, assistance with maintaining the fish breeding colonies, or assistance performing euthanasia. NOTE: This request must be submitted separately to the Animal Resources Program Office (ARPO)
11. Laboratories where Animal Procedures will be Conducted

Section AA - Agents Administered to Animals

As defined by the ORD SHEMF Office, a particularly hazardous agent exhibits one or more of these characteristics

- OSHA (GHS) Acute Toxicity Hazard Categories 1 and 2
 - Has an oral LD50 acute toxicity value (rat) \leq 50 mg/kg body weight
 - \circ Has an inhalation LC50 acute toxicity value (rat) \leq 2 mg/liter or \leq 500 ppm
 - \circ Has a dermal LD50 acute toxicity value (rat or rabbit) \leq 200 mg/kg body weight
 - Has an occupational exposure limit (OSHA, NIOSH or ACGIH) ≤ 1 ppm
- Causes carcinogenic effects (confirmed or suspected in humans and/or confirm animals) OSHA (GHS) Carcinogen Categories 1 and 2
- Causes teratogenic, mutagenic or reproductive effects (in humans or animals) OSHA (GHS) Categories 1 and 2 for Germ Cell Mutagenicity and Reproductive Toxicity

- Is an infectious biological agent, including human cell lines, human blood, or other potentially infectious materials (as defined by CDC and/or NIH)
- Is an explosive or violently reactive agent (shock sensitive, peroxide-forming (Category A-forming explosive levels of peroxides without concentration), and/or incompatible with moisture/air
- Is a respiratory or skin sensitizing agent
- Nanoparticle research involving the use of manufactured nanoparticles (metal oxides, carbon nanotubes, nano silica, etc.) not contained in solution and/or with the possibility of airborne exposure
- Is an agent whose toxicological characteristics are unknown, but it is suspected of meeting one of the above criteria

EXCEPTION: Standards ordered from vendors in sealed vials or ampoules that used directly in laboratory instrumentation are exemption even if they meet the above criteria.

Туре		
Agent		
HSRP		
Pharmaceutical Grade?		

Hazardous Agent
[Yes / No]
Controlled Substance?
[Yes / No]
Dose
Volume
Volume
D () 1 D 50
RouteAppropriate LD50 An example of a route appropriate Lethal Dose 50% (LD50) for specific species would be: Nicotine acute oral LD50 for the mouse is
3.34 mg/kg.

Route
Source
Maximum Dosing Level Examples for dosing would be: μg/kg or mg/kg for doses delivered directly to an animal via injection or other mean, ppm for concentrations of compounds inhaled or in drinking water, etc.
RouteAppropriate LD50 An example of a route appropriate Lethal Dose 50% (LD50) for specific species would be: Nicotine acute oral LD50 for the mouse is 3.34 mg/kg.

2. Do you plan to administer human or animal tissues, or body fluids?
[Yes / No]
2.1. Description of administration of human or animal tissues, or bodily fluids. Describe how it is known that pathogens are not being carried.
Section ABC - Animal Breeding Colonies
1. Does this ACUP have animal breeding colonies:
[Yes / No]
2. Estimated number of breeding pairs and liveborn per year:

Breeding colonies are complicated, and too much to cover here. If you need help setting one up, visit the NHEERL IACUC page or contact Exemption 6 3. Describe breeding protocols and recordkeeping: 4. Describe methods for monitoring genetic stability: 5. Describe disposition of all offspring and retired breeders that are not used in accordance with the procedures described in this ACUP:

Section EU - Euthanasia

1. When will the animals be euthanized relative to experimental procedures? Please make sure all categories of animals are covered.
Physical Euthanasia Methods
Method
Source
Explanation
Death Confirmation Description

2. Describe the disposition of any animals remaining after project completion
3. Would you consider transferring any unused animals from this ACUP to another approved ACUP
The IACUC encourages investigators to reduce the overall number of animals used
[Yes / No]
Section ASR - Assurances
Name
Name
Role

Date			

- Animals will not be used in any manner beyond that described in this application without first obtaining formal approval of the IACUC.
- All individuals involved in this project have access to this application, are aware of all EPA policies on animal care and use, and are appropriately trained and qualified to perform the techniques described.
- Thorough consideration of the three "R"'s (Replacement, Reduction, Refinement) has been given, as applicable, to a. the use of animals, and b. procedures causing pain or distress (with or without analgesia/anesthesia), including death as an endpoint. The minimum number of animals required to obtain valid experimental results will be used.
- The Attending Veterinarian has been consulted in regard to any planned experimentation involving pain or distress to animals.
- The IACUC and Attending Veterinarian will be promptly notified of any unexpected study results that impact the animals' well-being, including morbidity, mortality and any occurrences of clinical symptoms which may cause pain or indicate distress.
- All procedures involving hazardous agents will be conducted in accordance with practices approved by the Safety, Health, and Environmental Management Office.
- I certify that I am familiar with and will comply with all pertinent institutional, state and federal rules and policies.
- The IACUC has oversight responsibilities for animal care and use, and may request consultation or feedback regarding the conduct of in vivo procedures, progress and accomplishments, and any problems encountered.

Section REV - Reviewers

Name		

Role

ACUP Amendment Form	
Section BI - Base Info	
1. Parent ACUP	
2. Describe Amendment Updates:	
3. Please describe the amendment	
4. Amendment Purpose	

State the purpose of this amendment including the benefit to health or ecology. Describe significant change(s) from the original protocol including new or modifications of procedures (e.g., anesthesia, surgery, testing, euthanasia), or additional agents administered to the animals. Include all descriptive information as required on an original protocol. Explain how the benefits from the knowledge gained from this research outweigh the costs to the animals used in this research. A new protocol may be required if changes are extensive. The justification for the change is required for IACUC review.
5. Assurance that Study is Not Unnecessary Duplication
6. Alternatives to Pain and Distress
Amendment Number

Principal Investigator
Alternate Contact
Amendment Agenda Date
Amendment Approval Date
Status
Section TM - Team Members

Name

Organization			
Role			
NHEERL Training			
Active			
Responsibilities			

Animal Training			
Section PRD - Pr	rocedures		
1. Description of ch	nanges in the location of	housing and/or procedures	
Animal Pain/Distre	ess Categories		

	Adult	Offspring
2. Category B	(none entered)	(none entered)
3. Category C	(none entered)	(none entered)
4. Category D	(none entered)	(none entered)
5. Category E	(none entered)	(none entered)

6.1. Provide scientific justification for restraint

7.1. Provide scientific justification for food or water restriction
8.1. Provide scientific justification for survival surgery
9.1. Provide scientific justification for non-survival surgery

Section REQ - Animal Requirements

Total Number of animals for duration of the ACUP

1. Animal Justification Provide justification for the number, sources, and/or strains of animals to be added. Include all descriptive information as required on the original ACUP.
2. Animals to be purchased from a Vendor for this study
3. Animals to be transferred from another ACUP/LAPR
4. Offspring produced onsite (used for data collection and/or weaned)

5. Strains
6. Special Assistance Requested Describe special assistance requested of the animal contract staff, including procedures and dosing. Please describe any Technical Service Requests which may be submitted to the Animal Resources Program Office to obtain Animal Care Staff assistance with animal procedures. Technical Service Requests can be submitted for such diverse assistance as assisting with oral lavage dosing or vaginal lavage, assistance transporting animals to or from High Bay, assistance with maintaining the fish breeding colonies, or assistance performing euthanasia. NOTE: This request must be submitted separately to the Animal Resources Program Office (ARPO)

Section AA - Agents Administered to Animals

As defined by the ORD SHEMF Office, a particularly hazardous agent exhibits one or more of these characteristics

- OSHA (GHS) Acute Toxicity Hazard Categories 1 and 2
 - Has an oral LD50 acute toxicity value (rat) \leq 50 mg/kg body weight
 - Has an inhalation LC50 acute toxicity value (rat) \leq 2 mg/liter or \leq 500 ppm
 - o Has a dermal LD50 acute toxicity value (rat or rabbit) ≤ 200 mg/kg body weight
 - o Has an occupational exposure limit (OSHA, NIOSH or ACGIH) ≤ 1 ppm
- Causes carcinogenic effects (confirmed or suspected in humans and/or confirm animals) OSHA (GHS) Carcinogen Categories 1 and 2

- Causes teratogenic, mutagenic or reproductive effects (in humans or animals) OSHA (GHS) Categories 1 and 2 for Germ Cell Mutagenicity and Reproductive Toxicity
- Is an infectious biological agent, including human cell lines, human blood, or other potentially infectious materials (as defined by CDC and/or NIH)
- Is an explosive or violently reactive agent (shock sensitive, peroxide-forming (Category A-forming explosive levels of peroxides without concentration), and/or incompatible with moisture/air
- Is a respiratory or skin sensitizing agent
- Nanoparticle research involving the use of manufactured nanoparticles (metal oxides, carbon nanotubes, nano silica, etc.) not contained in solution and/or with the possibility of airborne exposure
- Is an agent whose toxicological characteristics are unknown, but it is suspected of meeting one of the above criteria

EXCEPTION: Standards ordered from vendors in sealed vials or ampoules that used directly in laboratory instrumentation are exemption even if they meet the above criteria.

Туре		
Agent		
HSRP		
Pharmaceutical Grade?		

Hazardous Agent
[Yes / No]
Controlled Substance?
[Yes / No]
Dose
Volume
Volume
RouteAppropriate LD50
An example of a route appropriate Lethal Dose 50% (LD50) for specific species would be: Nicotine acute oral LD50 for the mouse is 3.34 mg/kg.

Route
Source
Maximum Dosing Level Examples for dosing would be: μg/kg or mg/kg for doses delivered directly to an animal via injection or other mean, ppm for concentrations of compounds inhaled or in drinking water, etc.
RouteAppropriate LD50 An example of a route appropriate Lethal Dose 50% (LD50) for specific species would be: Nicotine acute oral LD50 for the mouse is 3.34 mg/kg.

Source
Other Source Description Justification and references are needed for any euthanasia agent or method that is not consistent with recommendations of the
American Veterinary Medical Association (AVMA) Guidelines for Euthanasia
1. Describe safety precautions for agents not covered by HSRP.
2. Do you plan to administer human or animal tissues, or body fluids?
[Yes / No] 3. Describe changes in disposition of used/unused animals.

Section ASR - Assurances		
Name		
- 142224		
Role		
Date		

- Animals will not be used in any manner beyond that described in this application without first obtaining formal approval of the IACUC.
- All individuals involved in this project have access to this application, are aware of all EPA policies on animal care and use, and are appropriately trained and qualified to perform the techniques described.
- Thorough consideration of the three "R"'s (Replacement, Reduction, Refinement) has been given, as applicable, to a. the use of animals, and b. procedures causing pain or distress (with or without analgesia/anesthesia), including death as an endpoint. The minimum number of animals required to obtain valid experimental results will be used.

- The Attending Veterinarian has been consulted in regard to any planned experimentation involving pain or distress to animals.
- The IACUC and Attending Veterinarian will be promptly notified of any unexpected study results that impact the animals' well-being, including morbidity, mortality and any occurrences of clinical symptoms which may cause pain or indicate distress.
- All procedures involving hazardous agents will be conducted in accordance with practices approved by the Safety, Health, and Environmental Management Office.
- I certify that I am familiar with and will comply with all pertinent institutional, state and federal rules and policies.
- The IACUC has oversight responsibilities for animal care and use, and may request consultation or feedback regarding the conduct of in vivo procedures, progress and accomplishments, and any problems encountered.

Name Role

Section REV - Reviewers

Annual Update Form

Annual Update to Approved Animal Care and Use Protocol

INSTRUCTIONS: Complete this form, sign, and forward to the IACUC Administrator. If you have any questions regarding completion of this form, please contact the IACUC Administrator, Exemption 6Exemption 6

Protocol Number: Click or tap here to enter text.
Protocol Title: Click or tap here to enter text.
Principal Investigator: Click or tap here to enter text.
STATUS OF PROJECT:
Request Protocol Termination (If you select one of these options, you do not need to complete the rest of the form. You may sign and submit to IACUC Administrator.) ☐ Inactive - project never initiated ☐ Currently inactive - project initiated has not/will not be completed. ☐ Completed - no further activities with animals will be done.
Request Protocol Continuance (If you select one of these options, please complete the rest of the form.)
 □ Active - project ongoing □ Currently inactive - project was initiated but is presently inactive □ Inactive - project never initiated but anticipated start date is:

RECORD OF ANIMAL USAGE

- 1. How many animals are authorized for use on this protocol?
 - a. Purchase or Transfer: Click or tap here to enter text.
 - b. Generated onsite: Click or tap here to enter text.
- 2. How Many animals have been used to date?
 - a. Animals ordered: Click or tap here to enter text.

 b. Animals Transferred: Click or tap here to enter te

- c. Born Onsite: Click or tap here to enter text.
- 3. For Breeding colonies only:
 - a. How many animals have been generated onsite this year? Click or tap here to enter text.
 - b. How many animals have been transferred to experimental Protocols this year? Click or tap here to enter text.
 - c. How many animals have been transferred to experimental Protocol over the life of this Protocol?Click or tap here to enter text.
- 4. Have there been any problems with human health and safety issues? \square Yes \square No

PROBLEMS/ADVERSE EVENTS: If the project is continuing and has been active for any time during the past 12 months, describe any unanticipated adverse events, morbidity or mortality, the cause(s), if known, and how these problems were resolved. If NONE, this should be indicated.

Click or tap here to enter text.

CERTIFICATION OF THE PRINCIPAL INVESTIGATOR

Signature certifies that the Principal Investigator understands the requirements of the PHS Policy on Humane Care and Use of Laboratory Animals, applicable USDA regulations and the Institution's policies governing the use of vertebrate animals for research, testing, teaching or demonstration purposes. Signature further certifies that the investigator will continue to conduct the project in full compliance with the aforementioned requirements.

Signature of the Principal Investigator

Date

Please attached a copy of the latest facilities	(including laboratory	inspections) and program	assessment report	conducted by the
IACUC/OB.			•	-



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

National Health and Environmental Effects Research Laboratory Research Triangle Park, NC 27711

OFFICE OF RESEARCH AND DEVELOPMENT

June 13, 2019

MEMORANDUM

SUBJECT: Semiannual Animal Facility Inspection Report

FROM: Exemption 6

Director, Animal Resources and Research Support

THRU: Michael Narotsky, Chair - NHEERL-Health IACUC M

TO: Wayne Cascio, Institutional Official - NHEERL Animal Program

On May 15, 2019, the semi-annual facility inspection was conducted for the EPA-RTP facilities that house animals or support their care and maintenance. The inspection team consisted of the following IACUC members: Mike Narotsky, Leslie Jarrell, Exemption 6Exemption 6

Exemption 6 the IACUC Administrator, also participated in the inspection. There were at least two IACUC members present for all USDA animal care and use areas observed.

The summary report was prepared and presented by Jaimie Graff at the IACUC quarterly business meeting on June 13, 2019. The full Committee reviewed and approved the evaluation. There were no minority views regarding the semiannual facility report.

The following facilities were inspected:

- · Building A primary housing areas, procedural spaces, and survival surgery areas
- · Building A cage wash areas, storage areas, and van used by the Animal Care staff
- Satellite Laboratories in B, E, and H buildings

The inspection team followed animal barrier standard operating procedures and safety principles during the inspection.

The facilities were found to have some potentially significant deficiencies, and many minor deficiencies. Significant deficiencies included the following:

- A counter top fume hood in the facility QA lab was not within certification. SHEM has worked to get the hood repaired. The hood is now deemed safe for use.
- 2. Fish tanks need to be rinsed with DI water after cage wash to remove potentially harmful soap residue, allowed to air dry, then stacked for storage. The observed tanks were stacked when wet and there is uncertainty about the regularity of rinsing. This may compromise fish health. New Operating Procedures for cleaning and rinsing tanks should be in place with the change in animal facility operations contract.

10000



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY National Health and Environmental Effects Research Laboratory Research Triangle Park, NC 27711

OFFICE OF RESEARCH AND DEVELOPMENT

June 13, 2019

MEMORANDUM

SUBJECT: Semiannual Evaluation of the Animal Care and Use Program

FROM:

Exemption 6 Director, Animal Resources and Research Support

THRU:

Michael Narotsky, Chair - NHEERL-Health IACUC MN

TO:

Wayne Cascio, Institutional Official - NHEERL Animal Program

Evaluation of the Animal Care and Use Program

The IACUC completed its semiannual evaluation of the institution's animal care and use program on May 8, 2019, in accordance with the 8th edition of the Guide for the Care and Use of Laboratory Animals (Guide), and, as applicable, 9CFR Chapter I, 2.31.

In attendance were: Mike Narotsky, Chair; Leslie Jarrell, Attending Veterinarian; Exemption 6 Exemption 6Exemption 6Exemption 6 and Research Support; and Exemption 6 IACUC Administrator.

The summary report was prepared and presented by Exemption 6at the IACUC quarterly business meeting on June 13, 2019. The full Committee reviewed and approved the evaluation as presented. (See attachment). There were no minority views regarding the semiannual program

In summary, the committee found the animal program to be consistent with the PHS Policy, the Guide, and applicable Animal Welfare Regulations. The significant deficiency concerning adequately trained animal care staff is being addressed with the change in the operations and maintenance contract for the animal facility. No further deficiencies need to be addressed.

Attachments

I. Semiannual Program Review and Facility Inspection Report

Date: May 15, 2019

Members in Attendance: Group A (1st, 2nd, 4th floors): Exemption 6Exemption 6Exemption 6 Leslie Jarrell; Group B (1st, 3rd and

5th floors): Exemption 6 Mike Narotsky, Exemption 6Exemption 6

Deficiency Category*	√	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
М		Through- Out Facility	Animal traps not checked on weekends and record sheets not with each trap (only 1 record for all traps on a floor).	Animal Facility Management (AFM)	Project Manager (PM) notified 6/10/19. Delay due to contract turnover	Corrected 6/8/19
М		A180	Need contact names on the door	AFM	PM notified 6/10/19	In progress 6/12/19
М		A194	Stored items within 18 inches of ceiling along walls	AFM	PM notified 6/10/19	
М		A194	Very cluttered and disorganized with lots of cardboard	AFM	PM notified 6/10/19	
М		A197	Needs Names for Emergency contacts	AFM	PM notified 6/10/19	In progress 6/12/19
М		A198	70% Ethanol on shelf expired 4/19	AFM	PM notified 6/10/19	Replaced 6/11/19
М		A198	No dates listed on Formalin samples in small countertop hood	AFM	PM notified 6/10/19	Completed 6/12/19
S		A198	Small countertop hood is not certified SHEM is working to assure the hood is safe for use as of 6/10/2019. If the hood is deemed unsafe, it will be replaced. Reviewed by SHEM, repaired by Wood, declared suitable	SHEM	This hood is obsolete and cannot be certified. Query sent to SHEM 6/10/19	Completed 6/12/19

М	A199E	Capsulated Brine shrimp, the facility now uses decapsulated, dispose	AFM	PM notified 6/10/19	
А	A199E	Cold room temp 43F and 84% humidity, is this within spec?			
		The Guide suggests storage at or below70F and 50% humidity, then notes that refrigeration (i.e. the cold room) preserves food better. Humidity in coolers tends to run higher, with 80+% not unusual.			
М	A199E	Need new sign on door with names of PI with Specialty Food	AFM	PM notified 6/10/19	Updated 6/12/19

* \mathbf{A} = acceptable

M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

√ Check if repeat deficiency

II. Semiannual Program Review and Facility Inspection Report

Date: May 15, 2019

Members in Attendance: Group A (1st, 2nd, 4th floors): Exemption 6Exemption 6Exemption 6

Leslie Jarrell; Group B (1st, 3rd and 5th floors): Exemption 6

Mike Narotsky, Exemption 6Exemption 6Exemption 6Exemption 6

Deficiency Category* √	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
М	A199E	Food stock need to be rotated, use oldest first	AFM	PM notified 6/10/19	

Α	A199E	Sunflower seeds, there are two open	AFM	PM notified 6/10/19
М	A199E	Powder feed in Red Barrel, Where's the labelled sheet?	AFM	PM notified 6/10/19
М	A floor	Long term storage of racks in the hall isn't permitted by either the fire marshal or AAALAC. Need to find long term storage for the metabolism cages.	AFM	PM notified 6/10/19
М	A197	B Rack washer-needs sign on red cord	AFM	PM notified 6/10/19
М	A197	Needs sign on metal button on the wall This would depend on what the button is for.	AFM	PM notified 6/10/19
М	A197	Warning surfaces are extremely hot is stuck to a wall behind tube. This requires clarification. Should the warning be somewhere	AFM	PM notified 6/10/19
М	A197	A Rack washer-needs sign on red cord	AFM	PM notified 6/10/19
М	Cage Wash	Faded emergency "push exit" sign	AFM	PM notified 6/10/19
М	Cage Wash	Faded emergency "stop" sign	AFM	PM notified 6/10/19
М	Cage Wash room	Outdated sound monitoring reports. Sound monitoring completed in 2018. New report replaced old posting 6/10/2019	SHEM	SHEM notified 6/10/2019 6/10/2019

^{*} **A** = acceptable

M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

 \checkmark Check if repeat deficiency

III. Semiannual Program Review and Facility Inspection Report

Date: May 15, 2019

Members in Attendance: Group A (1st, 2nd, 4th floors): Exemption 6Exemption 6Exemption 6 Leslie Jarrell; Group B (1st, 3rd and

5th floors): Exemption 6 Mike Narotsky, Exemption 6Exemption 6

Deficiency Category* √	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
М	A280A	There are 2 artemia cones. Why? How long are cultures kept? to fed to fish? Need labels on cones with dates	AFM	PM notified 6/10/19	
М	A280A	Metal ring stand on sink is very rusty needs replacing	AFM/ARPO	If someone would identify a replacement, ARPO can purchase	
М	A280A	Sharps bucket in hood is almost full and needs replacing	AFM	PM notified 6/10/19	
М	A280A	4 full glass waste jugs under hood dated 4/11, 4/19, 4/24 and 4/26. Please dispose of properly. Holding waste beyond 30 days is frowned on by SHEM.	AFM	PM notified 6/10/19	
М		Daily room records, the signs for Ph, Temperature, etc are backwards. Please train employees how to fill out records.	AFM	PM notified 6/10/2019	
М	A280 suite	On daily room record there should be information about acceptable range for room temp and humidity. Fish room temperatures are more applicable than humidity	AFM	PM notified 6/10/2019	In progress 6/12/19
М	A280B	Airgas tank needs to be removed, it's empty.	Research staff	notified 6/13/2019	

^{*} **A** = acceptable

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

√ Check if repeat deficiency

IIII. Semiannual Program Review and Facility Inspection Report

Date: May 15, 2019

Members in Attendance: Group A (1st, 2nd, 4th floors): Exemption 6Exemption 6Exemption 6 Leslie Jarrell; Group B (1st, 3rd and

5th floors): Exemption 6 Mike Narotsky, Exemption 6Exemption 6

Deficiency Category*	√	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
М		Cage Wash room	Condensation line leak from ceiling mounted compressor	ARPO	Service call submitted 6/10/19	
М		Cage Wash room	Electric shut off box blocked- 36" egress is needed Bedding relocated 6/12/19.	AFM	PM notified 6/10/19	Complete 6/12/19
М		A195	Need Fire Extinguisher	ARPO	Service call for replacement submitted 6/10/19	
М		2 nd floor	Ceiling Tile outside of elevator is ajar	ARPO	Service call submitted 6/10/19	
М		Through- out facility	Animal Facility Contact signs needs updating	ARPO	In progress, begun 6/6/19. Need contact info for new PM	
М		2 nd floor	Rusty carts need replacing Throughout facility. Carts are being identified and prioritized for repair/replacement.	ARPO/AFM	PM notified 6/10/19	In progress 6/12/19

М	A280D	Fish filters are dirty and need replacement or cleaning	AFM	PM notified 6/10/19	complete
		Filters are being replaced as needed.		Likely resolved earlier	
М	A280 Suite	Non-regulated waste bottles (Full) Moved to Chemical Waste 6/12/19	AFM	PM notified 6/10/19	Complete 6/12/19

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S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

√ Check if repeat deficiency

IV. Semiannual Program Review and Facility Inspection Report

Date: May 15, 2019

Members in Attendance: Group A Group A (1st, 2nd, 4th floors): Exemption 6Exemption 6Exemption 6

Leslie Jarrell; Group B (1st, 3rd and 5th floors): Exemption 6

Mike Narotsky, Exemption 6Exemption 6Exemption 6

Deficiency Category*	√	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
М		A280B	Airtank, regulator needs to be removed within 14 days on not being used.	AFM	PM notified 6/10/2019	
М		A280B	Electric box/Power strip should not be laying on the floor, mount to floor or a table	AFM	PM notified 6/10/2019	

S	A280C	Housing Tanks need to be rinsed with DI water after cage wash, allow air dry, then stack. The current tanks were stacked when wet.	AFM	PM notified 6/10/2019	6/13/19
		Ongoing issue, period problems with what look like soap residue from not being rinsed.			
М	A280 Hallway	All liquid waste containers need secondary containers Secondary containment placed 6/13/19	AFM	PM notified 6/10/2019	6/13/19
М	A280 Hallway	Can LaMotte Kit waste be mixed with other waste?	ARPO	Checking with SHEM waste management	In progress
М	A280 Hallway Cabinet	All liquids should be in secondary containers Secondary containment placed 6/13/19	AFM	PM notified 6/10/2019	6/13/19
М	A280E,F,G	Racks do not have baffles on ALL tanks as approved on TSR Marked with green sticker for daily water dumping	AFM	PM notified 6/10/2019	6/13/19

* \mathbf{A} = acceptable

M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

 \checkmark Check if repeat deficiency

V. Semiannual Program Review and Facility Inspection Report

Date: May 15, 2019

Members in Attendance: Group A (1st, 2nd, 4th floors): Exemption 6 Exemption 6 Exemption 6 Leslie Jarrell; Group B (1st, 3rd and 5th floors): Exemption 6 Mike Narotsky, Exemption 6 Exemption 6 Exemption 6

Deficiency Category*	√	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
М		A280E,F,G	Fish food accumulation on lids needs to be cleaned off. Cleaned off weekly	AFM	PM notified 6/10/2019	6/12/19
		A280F	Floor drain is uneven in the back corner This requires clarification. Was the cover uneven? The drain itself is set into the floor and is meant to be uneven.			
M/S		A280E,F,G	All Aquaneering racks; are the power strips the correct rating for use? Power strips around water should be GFI or otherwise rated for being around water, and need to be anchored in place on the racks. The power strips on the racks seem to be random ratings. Checking for water compatibility would be a good idea.	AFM	PM notified 6/10/2019	Under review 6/12/19
М		A280E,F,G	Pre-filter pads were dirty Replaced end of the day on 6/12/19	AFM	PM notified 6/10/2019 Likely resolved already	6/12/19
М		A280E	Mini-MEPs A & B interior sides had a lot of algae buildup. MEPS are being added to husbandry sheet	AFM	PM notified 6/10/2019	In progress 6/12/19
М		A280E	A lot of tanks had a lot of algae buildup. Tanks with build-up changed out	AFM	PM notified 6/10/2019	6/11/19
M/C		A280E	RO storage tank had excessive algae buildup. ARPO has already ordered another storage tank. Waiting for delivery, at which point it will be installed, filled, and the first tank will be thoroughly cleaned.	ARPO/AFM	PM notified 6/10/2019	

М	A280E,F,G	RO water supply lines and water recirculation lines had excessive algae buildup.	ARPO/AFM	PM notified 6/10/2019
		ARPO is working with the research staff to update the		
		Aquaneering systems. Replacement of water lines can be		
		discussed between the AFM and ARPO		

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M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

√ Check if repeat deficiency

VI. Semiannual Program Review and Facility Inspection Report

Date: May 15, 2019

Members in Attendance: Group A Group A (1st, 2nd, 4th floors): Exemption 6Exemption 6Exemption 6

Leslie Jarrell; Group B (1st, 3rd and 5th floors): Exemption 6

, Mike Narotsky, Exemption 6Exemption 6Exemption 6

Responsible Correction Schedule Deficiency Deficiency and Date **Party** Category* Location Plan for Correction and Interim Status **Complete** 3rd floor Unlocked electric panel X631 Service call placed М OARM 6/10/19 M/C A380A No sentinels in the Animal Room AFM/ARPO Sentinel animals were distributed throughout Sentinel animals were distributed throughout the facility 5/29/19 in the facility 5/29/19 response to an incident with a room of sneezing animals that had no sentinels. Further review of the sentinel program and procedures will

M/C	A380E	No sentinels in the Animal Room	AFM/ARPO	Sentinel animals were distributed throughout the facility 5/29/19
М	A390B	Expired Isoflurane Original owner of chemical is responsible for disposal. Whose name is on the bottle? This individual should be notified. If there is not name ARPO will dispose of the chemical	Research staff	
М	A390D	Expired Saline See above	Research staff	
М	A390C	Formalin containers for specimen, needs secondary container See above	Research staff	
M/C	A386	No sentinels in the Animal Room	AFM/ARPO	Sentinel animals were distributed throughout the facility 5/29/19

* **A** = acceptable

M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

 \checkmark Check if repeat deficiency

VII. Semiannual Program Review and Facility Inspection Report

Date: May 15, 2019

Members in Attendance: Group Group A (1st, 2nd, 4th floors): Exemption 6Exemption 6Exemption 6 Leslie Jarrell; Group B (1st,

3rd and 5th floors): Exemption 6 Mike Narotsky, Exemption 6Exemption 6

Deficiency Category*	✓	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
М		A477	No animals in the suite, still had old trash including bedding in trash can.	AFM	PM notified 6/10/19	Completed 6/12/19
М		A477	Daily room record is old. Still on clip board, dated 4/22/2019	AFM	PM notified 6/10/19	Removed 6/12/19
		A477A	Water line plugged, stagnant water is present Water line for what? Were animals drinking this stagnant water? Clarification is required. Checked for water 6/12/19; no water present	AFM	PM notified 6/10/19	6/12/19
М		A492B	No Sani Cloths present	AFM	PM notified 6/10/19	6/12/19
М		A476	Step Stool in front on eye wash, blocking access Removed 6/11/19	AFM	PM notified 6/10/19	6/11/19
М		A479G	Cap cover on eye wash is broken	SHEM/OARM	Service call submitted 6/10/2019.	
М		A479G	Gas tank not being used on regular basis, take regulator off.	AFM/Research staff	PM notified 6/10/19	Still in use 6/12/19
M		A479G	Under BSC in plastic container, individual boxes of liquid and specimens need to be individually labelled.	Research staff	Research Staff notified 6/13/2019	

* **A** = acceptable

M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

 \mathbf{C} = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

√ Check if repeat deficiency

VIII. Semiannual Program Review and Facility Inspection Report

Date: May 15, 2019

Members in Attendance: Group A Group A (1st, 2nd, 4th floors): Exemption 6Exemption 6Exemption 6 Leslie Jarrell; Group B

(1st, 3rd and 5th floors): Exemption 6 Mike Narotsky, Exemption 6Exemption 6

Deficiency Category* √	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
М	A479G	Guillotines need record of last sharpening on instrument or in a identifiable log	n Research Staff	Staff needs to be notified. Who owns this equipment?	
М	A479E	70% ethanol should not be stored under sink	Research Staff	Research Staff notified 6/13/2019	

M/S	A479 Suite	2 Animal Health Reports not followed up on since 5/3/2019 Following IACUC inspection the AV reviewed all open animal health reports, and found several animals that had not been reseen, as well as a number of animals whose health reports should have been closed as resolved and were not. Fortunately, the animals were all recovering well and there were no animal welfare issues. There was a significant problem with the performance of the animal health specialist. This individual was not retained in that position when the contract turned over.	AFM/Animal Health Specialist	Following the IACUC inspection the AV followed up on all animal health reports	5/24/2019
М	A479A	Egress is blocked by a cart. Inspector moved cart.	AFM	PM notified 6/10/19	5/15/19
М	A479A	Clutter in room, needs cleaning	Research Staff	Staff needs to be notified. Exemption 6	
А	A479A	Water maze has not been used, maybe store somewhere else? Decision can be made based on space requirements	ARPO		
М	A479G	Lights do not turn off No animals in the room; not a welfare issue. Waste of energy.	ARPO	Service call submitted 6/10/2019	
М	A479 in hall	2 ceiling tiles ajar, around sprinkler	ARPO	Service call submitted 6/10/2019	
М	A499E	Missing ceiling tiles	ARPO	Service call submitted 6/10/2019	

^{*} **A** = acceptable

M = minor deficiency

 \mathbf{S} = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

√ Check if repeat deficiency

IX. Semiannual Program Review and Facility Inspection Report

Date: May 15, 2019

Members in Attendance: Group A (1st, 2nd, 4th floors): Exemption 6Exemption 6Exemption 6 Leslie Jarrell; Group B (1st, 3rd and

5th floors): Exemption 6 Mike Narotsky, Exemption 6Exemption 6

Deficiency Category*	√	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
М		Through- out	Animal Facility Emergency Guide needs updating This update will take place once staff turnover is complete.	ARPO	holding	
М		A499C	Empty cardboard box and trash littering the floor	AFM	PM notified 6/10/19; likely resolved already	6/12/19
М		A486E	Empty cages on left side of room, supposed to be clean but still had rabbit hair, urine scale and hay in them. Clean caging should be confirmed actually clean before being	AFM	PM notified 6/10/19	6/12/19
S		A486E	1 Rabbit not socially housed. Social housing of rabbits has been emphasized by AAALAC over the last few years. ARPO has gone to some effort to provide caging capable of social housing. Please use it thoughtfully.	AFM	PM notified 6/10/19 New housing put into use, animals will be rotated through social housing	6/12/19
М		A486E	Hay in the room does not match vet requirements listed on email attached to door of A486D	AFM	PM notified 6/10/19	Area sanitized 6/12/19
M/S		A486D	Undated water bottles on exercise pens Some water bottles were looking pretty old and nasty. Rabbits	AFM	PM notified 6/10/19	No bottles present 6/12/19

M/S	A486 suite	Health report on 4/25/2019 is not followed. Animal last checked on 5/2/2019 No current animal welfare issues.	AFM/Animal Health Specialist	See earlier note about AV following up on all open health reports.	
М	A486 suite	Personnel list on door is outdated	Research staff	Research staff needs to be notified.	

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M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

 \mathbf{C} = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

 \checkmark Check if repeat deficiency

X. Semiannual Program Review and Facility Inspection Report

Date: May 15, 2019

Members in Attendance: Group A (1st, 2nd, 4th floors): Exemption 6Exemption 6Exemption 6

Leslie Jarrell; Group B (1st, 3rd and 5th floors)

Mike Narotsky, Exemption 6Exemption 6Exemption 6Exemption 6

Deficiency Category*	√	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
М		A486	Door Jam need painting	ARPO/AFM	See note under Deficiency	
			Touch up painting is probably required throughout facility. ARPO and AFM will work together to compile areas in need of attention, and submit a		,	

М	Main hall	Ceiling tile is bulging	ARPO	Service call submitted	
	outside			6/10/2019	
	A462A				
М	A489D	Fire detector is inside of ceiling.	SHEM/OARM	Service call submitted 6/10/2019	
M	A490F	Sticky substance is running down the drawer	AFM	PM notified 6/10/19	
		All the drawers and pull out surfaces had an odd, oily sticky			
		material running down from the stops and puddling on the floor.			
		No idea what the material is or where it came from. Probably not			
A	A490D	Does autoclave need certification? Current performance meets QA standards	SHEM/OARM	SHEM and OARM are looking into the maintenance and testing	6/12/19 facility te working
				needs of the sterilizers.	sterilze
М	A490D	Trashcan not emptied in a while	AFM	PM notified 6/10/19, potentially already resolved.	Complete 6/12/19

^{*} **A** = acceptable

C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

 \checkmark Check if repeat deficiency

XI. Semiannual Program Review and Facility Inspection Report

Date: May 15, 2019

Members in Attendance: Group A (1st, 2nd, 4th floors): Exemption 6Exemption 6

Leslie Jarrell; **Group B** (1st, 3rd and

5th floors): Exemption 6 Mike Narotsky, Exemption 6Exemption 6

Deficiency Category*	√ Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
М	A490F	Compressed Oxygen has 2 tags (1 is taped), please attach the tags	AFM	PM notified 6/10/19	6/12/19
М	A490D	Bench top is oily.	AFM	PM notified 6/10/19	6/12/19
М	A490D	Rabbit humidity container needs to be excessed	ARPO	Not urgent, just takes up extra space.	
М	A490 suite	Phone is missing backing part. Please repair	ARPO	Service call submitted 5/15. Check on completion	
	A490B	Change Post it note to a permanent sign "Do not touch switch" Requires some clarification for why the switch can't be touched.		COMMISSION	
N/A	A490C	Old animal health report hang tags found and removed by IACUC	ARPO/IACUC	Complete. Just a clean up detail.	
N/A	A490C	Old Klinefelter animal cage card found and removed by IACUC.	ARPO/IACUC	Complete. Just a clean up detail.	
М	A490C	Found an empty CO2 tank, needs to be removed.	AFM	PM notified 6/10/19	6/12/19

* **A** = acceptable

M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

√ Check if repeat deficiency

XII. Semiannual Program Review and Facility Inspection Report

Date: May 15, 2019

Members in Attendance: Group A (1st, 2nd, 4th floors): Exemption 6Exemption 6Exemption 6 Leslie Jarrell; Group B (1st, 3rd and

5th floors): Exemption 6 Mike Narotsky, Exemption 6Exemption 6

Deficiency Category* √	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
М	A490C	Refrigerator had lots of standing water; unidentified source	AFM	PM notified 6/10/19	6/12/19: No water present
М	A490C	Refrigerator need signage. "No food allowed"	AFM	PM notified 6/10/19	Sign posted 6/12/19
М	A490C	Ice machine need signage. "Not for human consumption"	AFM	PM notified 6/10/19	
М	A584	Light over sink next to wall will not turn on.	ARPO	Service call submitted 6/10/19.	
N/A	A584	Clock needs new batteries Who does the clock belong to? Batteries replaced 6/13/19 by AFM. Thank you.			6/13/19
M/S	A576A	No Sentinels in the Animal room No animal welfare issues, but ties to earlier finding.			
М	A578B	Gas cylinder tank is not secured	Research Staff	Research staff should be notified.	
М	A557A	Burn Box is full	Research Staff	Research staff should be notified.	

* **A** = acceptable

M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

 \mathbf{C} = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

 \checkmark Check if repeat deficiency

XIII. Semiannual Program Review and Facility Inspection Report

Date: May 15, 2019

Members in Attendance: Group A (1st, 2nd, 4th floors): Exemption 6Exemption 6Exemption 6 Leslie Jarrell; Group B (1st, 3rd and

5th floors): Exemption 6 Mike Narotsky Exemption 6Exemption 6

Deficiency Category* √	Location	Deficiency and Responsible Plan for Correction		Correction Schedule and Interim Status	Date Complete
М	A599J	36in egress is needed on eye wash	Research Staff	Research staff should be notified.	
М	A599F	Electric plug box is hanging open	Research Staff	Research staff should be notified.	
М	A561A	Burn box is full	Research Staff	Research staff should be notified.	
М	A599H	Personnel sign needs updating	ARPO/AFM	In progress	
М	A578 Suite	Inner sink does not work	ARPO	Service call submitted 6/10/19.	
М	A579E	Contact list needs updating	Research Staff	Research staff should be notified.	
M/S	A579A, A277	Animals look large, need body weights for housing density. A potential concern for both Animal Care Staff and researchers.		Research staff should be notified.	
М	5 th floor hall	Electric panels are open (not locked) X654, X652, X651	ARPO	Service call submitted 6/10/19.	

^{*} **A** = acceptable

M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

√ Check if repeat deficiency

XIV. Semiannual Program Review and Facility Inspection Report

Date: May 15, 2019

Members in Attendance: Group A (1st, 2nd, 4th floors): Exemption 6Exemption 6Exemption 6 Leslie Jarrell; Group B (1st, 3rd and

5th floors): Exemption 6 Mike Narotsky, Exemption 6Exemption 6

Deficiency Category*	√	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
М		A585 Suite	Sink is not working	ARPO	Service call submitted 6/10/19.	
М		A599C	No contact names on the door Throughout facility	ARPO/AFM	Update is in progress. See earlier comments.	
М		A599D	No contact names on the door	ARPO/AFM	Update is in progress. See earlier comments.	
М		A587A	Secondary containers are needed for solutions These solutions are likely for the Training classes. ARPO will provide secondary containment or discard the solutions	ARPO	Replace or discard within 2 months; provide secondary containment if replaced.	
М		A587A	Dermachlor solution is expired These solutions are likely for the Training classes.	ARPO	Replace or discard within 2 months; provide secondary containment if replaced.	
М		A587A	Hibiclens is expired These solutions are likely for the Training classes.	ARPO	Replace or discard within 2 months; provide secondary containment if replaced.	

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M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

 \checkmark Check if repeat deficiency

XV. Semiannual Program Review and Facility Inspection Report

Date: May 16, 2019

Members in Attendance: Exemption 6 and Exemption 6

Deficiency Category* √	Location	Deficiency and Responsible Plan for Correction	Correction Schedule and Interim Status	Date Complete
N/A	High Bay	Not ready for animal use Research staff	Will review when recommissioned	
N/A	H106C	BSC has not been certified for use Research staff	Will review when recommissioned	

* A - acceptable		

* A = acceptable

M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

√ Check if repeat deficiency

XVI. Semiannual Program Review Checklist 1

Institutional Policies and Responsibilities

Date: May 8, 2019

A M S C NA

 Responsibility for animal well-being is assumed by all members of the program (Guide, p 1) [must]

 IO has authority to allocate needed resources (Guide, p 13)

¹ The PHS Policy requires that Assured institutions comply with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act, as applicable. The endnotes below are specific USDA regulatory requirements that differ from or are in addition to the PHS Policy. This list is not intended to be all inclusive. For additional information please refer to 9 CFR Subchapter A - Animal Welfare.

	Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the <i>Guide</i> (<i>Guide</i> , pp 11, 15)	X			X	
•	Program needs are regularly communicated to IO by AV and/or IACUC (Guide, p 13)	^				_
	Responsibilities for daily animal care and facility management are assigned to specific individual(s) when a full-time veterinarian is not available on site ($Guide$, p 14) [must]					X
•	Inter-institutional collaborations are described in formal written agreements ($Guide$, p 15)	X				
•	Written agreements address responsibilities, animal ownership, and IACUC oversight ($Guide$, p 15)					X
. Di	saster Planning and Emergency Preparedness	A*	М	S	С	N
*	Disaster plans for each facility to include satellite locations are in place (<i>Guide</i> , <u>p 35</u> , <u>p 75</u>) [must]There have been improvements to the fish emergency response plans	X			X	
	Plans include provisions for euthanasia (<i>Guide</i> , <u>p 35</u>) [must]	X				
	Plans include triage plans to meet institutional and investigators' needs (<i>Guide</i> , <u>p 35</u>)	X				
•	Plans define actions to prevent animal injury or death due to HVAC or other failures $(Guide, p 35)$	X				
	Plans describe preservation of critical or irreplaceable animals (Guide, p 35)	X				
	Plans include essential personnel and their training (Guide, p 35)	X				
	Animal facility plans are approved by the institution and incorporated into overall response plan (<i>Guide</i> , p 35) improvements following government shutdown	X			X	
•	Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (Guide, p 35) improvements following government shutdown	X			X	
		A*	M	S	C	NI

•	IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (<i>Guide</i> , <u>p 26</u>) [must]	X				
	Continuing IACUC oversight after initial protocol approval is in place (Guide, p 33)	X				
	IACUC evaluates the effectiveness of training programs (Guide, p 15)				X	
. 14	ACUC Protocol Review - Special Considerations	A*	M	S	C	NA
٠		x			x	
	For pilot studies, a system to communicate with the IACUC is in place (Guide, p 28)	X				
*	For genetically modified animals, enhanced monitoring and reporting is in place ($Guide$, p 28)	X				
*	Restraint devices are justified in the animal use protocols (<i>Guide</i> , <u>p 29</u>) [must]	X				
	Alternatives to physical restraint are considered (Guide, p 29)	X				
	Period of restraint is the minimum to meet scientific objectives (Guide, p 29)	X				
	Training of animals to adapt to restraint is provided (Guide, p 29)	X				
	Animals that fail to adapt are removed from study (Guide, p 29)	X				
	Appropriate observation intervals of restrained animals are provided (Guide, p 29)	X				
•	Veterinary care is provided if lesions or illness result from restraint (<i>Guide</i> , <u>p 30</u>) [must]	X				
•	Explanations of purpose and duration of restraint are provided to study personnel (Guide, p 30)	X				
•	Multiple surgical procedures on a single animal are justified and outcomes evaluated (Guide, p 30)					X

			-				_
	٠	Major versus minor surgical procedures are evaluated on a case-by-case basis (<i>Guide</i> , p 30)	X				
	•	Multiple survival procedure justifications in non-regulated species conform to regulated species standards (<i>Guide</i> , p 30)					X
	٠	Animals on food/fluid restriction are monitored to ensure nutritional needs are met $(Guide, p 31)$	X				
	•	Body weights for food/fluid restricted animals are recorded at least weekly ($Guide$, p 31)	X				
		Daily written records are maintained for food/fluid restricted animals (<i>Guide</i> , <u>p 31</u>)	X				
	•	Pharmaceutical grade chemicals are used , when available, for animal-related procedures (<i>Guide</i> , <u>p 31</u>)	X				
	٠	Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC (Guide, p 31)	X				
	٠	Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area (<i>Guide</i> , p.32)					X
		Disposition plans are considered for species removed from the wild (<i>Guide</i> , <u>p 32</u>)					X
	٠	Toe-clipping only used when no alternative, performed aseptically and with pain relief $(Guide, p.75)$					X
5.	IA	ACUC Membership and Functions	A*	M	S	C	NA
		IACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, IV.A.3.)	X				
	•	Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab animal user $(Guide, p.24)^2$	X				
	٠	IACUC authority and resources for oversight and evaluation of institution's program are provided (<i>Guide</i> , p. 14)	X				

² Part 2 Subpart C - Research Facilities

^{- 2.31(}b)(2) - "The Committee shall be composed of a Chairman and at least two additional members;... at least one shall not be affiliated in any way with the facility...such person will provide representation for general community interests in the proper care and treatment of animals." [PHS policy requires 5 members]

•	All IACUC members should receive:	X				
I	ACUC Training NEW	A*	М	S	С	N
*	Requests for exemptions from major survival surgical procedure restrictions are made to USDA/APHIS 5 (<i>Guide</i> , p 30) [must])
•	Policies are in place for special procedures (e.g., genetically modified animals, restraint, multiple survival surgery, food and fluid regulation, field investigations, agricultural animals) (<i>Guide</i> , p 27-32)	X				
•	Procedures are in place for review and approval of significant changes to approved activities (PHS Policy, IV.B.)	X				
•	Procedures are in place for review, approval, and suspension of animal activities ⁴ (PHS Policy, <u>IV.B.</u>)	X				
•	Reviews and investigates concerns about animal care and use at institution ³ (PHS Policy, <u>IV.B.</u>)	X				
•	Methods for reporting and investigating animal welfare concerns are in place (<i>Guide</i> , <u>p</u> <u>23</u>) [must]					Į
•	IACUC organizationally reports to the Institutional Official (PHS Policy, IV.A.1.b.)	X				
٠	Conducts semiannual inspections of institutional animal facilities (PHS Policy, <u>IV.B.</u>)	X				
•	IACUC conducts semiannual evaluations of institutional animal care and use program (PHS Policy, $\underline{\text{IV.B.}}$)	X				

³ 2.32(c)(4) - "...No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act." [USDA requirement additional to PHS Policy]

⁴ 2.31(d)(5) - "...shall conduct continuing reviews of activities...not less than annually." [PHS Policy requires a complete new review every 3 years utilizing all the criteria for initial review]

⁵ 2.31(d)(1)(x) - "...no animal will be used in more than one major operative procedure from which it is allowed to recover unless...(it is) justified for scientific reasons...(or is) required as routine veterinary procedure...or other special circumstances as determined by the Administrator on an individual basis." [this last point is an additional USDA justification for multiple survival surgeries]

	 Training on legislation, regulations, guidelines, and policies (Guide, p 17) 	X				
	Training on how to inspect facilities and labs where animal use or housing occurs (Guide, p 17)	X				
	Training on how to review protocols as well as evaluate the program (Guide, p 17)	X				
	o Ongoing training/education (Guide, p 17)	X				
TΔ	CUC Records and Reporting Requirements ⁶	A*	М	S	C	NA
•	Semiannual report to the IO (PHS Policy, <u>IV.B.</u>)					
	Submitted to IO every 6 months	X				
	 Compiles program review and facility inspection(s) results (includes all program and facility deficiencies) 	X				
	 Includes minority IACUC views there were none during this review period; otherwise would be included. 					X
	Describes IACUC-approved departures from the <i>Guide</i> or PHS Policy and the reasons for each departure ⁷	X				
	Distinguishes significant from minor deficiencies	X				
	 Includes a plan and schedule for correction for each deficiency identified⁸ 	X				
	Reports to OLAW (PHS Policy, IV.F.)					

⁶ 2.36 - "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]

⁷ 2.36(b)(3) - "...exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report." [Refers to USDA annual report]

⁸ 2.31(c)(3) - "...Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the institutional official, to APHIS and any Federal agency funding that activity." [PHS Policy requires prompt reporting to OPRR of serious or continuing noncompliance with the PHS Policy or serious deviations from the provisions of the *Guide*]

0	Annual report to OLAW documents program changes, dates of the semiannual program reviews and facility inspections and includes any minority views	X	
0	Promptly advises OLAW of serious/ongoing <i>Guide</i> deviations or PHS Policy noncompliance (NOT-OD-05-034)	X	
0	Institute must promptly advise OLAW of any suspension of an animal activity by the IACUC (NOT-OD-05-034)	X	
• Re	ports to U.S. Department of Agriculture (USDA) or Federal funding agency ⁹		
0	Annual report to USDA contains required information including all exceptions/exemptions	X	
0	Reporting mechanism to USDA is in place for IACUC-approved exceptions to the regulations and standards <i>there were none during this review period; otherwise would be included.</i>		X
0	Reports are filed within 15 days for failures to adhere to timetable for correction of significant deficiencies there were none during this review period; otherwise would be included.		X
0	Promptly reports suspensions of activities by the IACUC to USDA and any Federal funding agency	X	
• Re	ecords (PHS Policy, <u>IV.E.</u>)		
0	IACUC meeting minutes and semiannual reports to the IO are maintained for 3 years	X	
0	Records of IACUC reviews of animal activities include all required information 10	X	

⁹ 2.36 - "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]

- 2.31(d)(1)(iii) "The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments."
- 2.31(d)(1)(iv) "Procedures that may cause more than momentary or slight pain or distress to the animals will:
 - involve in their planning, consultation with the attending veterinarian or his or her designee; [PHS Policy does not specify veterinary consultation]
 - not include paralytics without the use of anesthesia;"
- 2.31(d)(1)(x) "No animal will be used in more than one major operative procedure from which it is allowed to recover, unless justified for scientific

¹⁰ In addition to PHS requirements for IACUC review/application for funding, USDA regulations require:

^{2.31(}d)(1)(ii) - "The principal investigator (PI) consider alternatives to procedures that cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources...used to determine that alternatives were not available."

				-	
 Records of IACUC reviews are maintained for 3 years after the completion of the study 	X				
3. Veterinary Care (See also next section - Veterinary Care)	A*	M	S	C	NA
 An arrangement for veterinarian(s) with training or experience in lab animal medicine is in place including backup veterinary care¹¹ 	X				
 Veterinary access to all animals is provided (Guide, p 14) [must] 	X				
 Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use (Guide, p 14) [must] 	X				
 Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol (Guide, p 5) [must] 	X				
 Veterinarian provides consultation when interventional control is not possible (Guide, 5) [must] 	X				
If part time /consulting veterinarian, visits meet programmatic needs (Guide, p 14)					X
Regular communication occurs between veterinarian and IACUC (Guide, p 14)	X				
 Veterinarian(s) have experience and training in species used (Guide, p 15) [must] 	X				
 Veterinarian(s) have experience in facility administration/management (Guide, p 15) 	X				
9. Personnel Qualifications and Training	A*	M	S	C	NA
 All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Personnel included: [must] 					
Veterinary/other professional staff (<i>Guide</i> , p 15-16)	X				

reasons by the principal investigator, in writing..."

¹¹ 2.33(a)(1) - "In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility." [USDA requirement additional]

	X			
o IACUC members (<i>Guide</i> , <u>p 17</u>)				
 Animal care personnel (Guide, p 16) Substantive changes are in progress; new contract, new training protocol 		X	X	
 Research investigators, instructors, technicians, trainees, and students (Guide, pp 16-17) 	X			
 Continuing education for program and research staff provided to ensure high quality care and reinforce training (<i>Guide</i>, pp 16-17) 	X			
 Training is available prior to starting animal activity (Guide, p 17) 	X		X	
Training is documented (Guide, p 15)	X			
 Training program content includes: (Guide, p 17) 				
 Methods for reporting concerns (Guide, p 17) 	X			
 Humane practices of animal care (e.g., housing, husbandry, handling) ¹² 	X			
 Humane practices of animal use (e.g., research procedures, use of anesthesia, pre- and post-operative care, aseptic surgical techniques and euthanasia (Guide, p 17)¹³ 	X			
 Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, <u>IV.A.1.g.</u>) 	X			
 Research/testing methods that minimize animal pain or distress (PHS Policy, IV.A.1.g.) 	X			

¹² 2.32(c) - "Humane methods of animal maintenance and experimentation, including the basic needs of each species, proper handling and care for the various species of animals used by the facility, proper pre-procedural and post-procedural care of animals, and aseptic surgical methods and procedures."

¹³ 2.32(c) - additional specifications include:

^{- &}quot;proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility"

^{- &}quot;methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility..."

^{- &}quot;utilization of services (e.g., National Agricultural Library, National Library of Medicine) to provide information on appropriate animal care and use, alternatives to the use of live animals in research, that could prevent unintended and unnecessary duplication of research involving animals, and regarding the intent and requirements of the Act." [USDA training specifications are more detailed than PHS Policy].

	 Use of hazardous agents, including access to OSHA chemical hazard notices where applicable (Guide, p 20) 	X				
	Animal care and use legislation (<i>Guide</i> , <u>p 17</u>)	X				
	o IACUC function (Guide, p 17)	X				
	o Ethics of animal use and Three R's (Guide, p 17)	X				
10.	Occupational Health and Safety of Personnel	A*	M	S	C	NA
•	Program is in place and is consistent with federal, state, and local regulations (<i>Guide</i> , p 17) [must]	X				
	Program covers <i>all</i> personnel who work in laboratory animal facilities (<i>Guide</i> , <u>p 18</u>)	X				
	Changing, washing, and showering facilities are available as appropriate (Guide, p 19)	X				
•	Hazardous facilities are separated from other areas and identified as limited access (Guide, p 19)	X				
٠	Personnel training is provided based on risk (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies) (<i>Guide</i> , p 20)	X				
•	Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking policies) (<i>Guide</i> , p 20)	X				
•	Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place (<i>Guide</i> , p 21)	X				
•	Personal Protective Equipment for the work area is appropriate and available (<i>Guide</i> , <u>p</u> <u>21</u>)	X				
•	Program for medical evaluation and preventive medicine for personnel includes:					
	Pre-employment evaluation including health history (<i>Guide</i> , <u>p 22</u>)	X				
	 Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate (Guide, p 22) 	X				
	 Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague) (Guide, p 23) 	X				

	 Procedures for reporting and treating injuries, including accidents, bites, allergies, etc. (Guide, p 23) 	X				
	 Promotes early diagnosis of allergies including preexisting conditions (Guide, p 22) 	X				
	 Considers confidentiality and other legal factors as required by federal, state and local regulations (Guide, p 22) [must] 	X				
	 If serum samples are collected, the purpose is consistent with federal and state laws (Guide, p 22) [must] 	X				
	Waste anesthetic gases are scavenged (<i>Guide</i> , <u>p 21</u>)	X				
	Hearing protection is provided in high noise areas (<i>Guide</i> , <u>p 22</u>)	X				
•	Respiratory protection is available when performing airborne particulate work (<i>Guide</i> , p 22)	X				
•	Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include:					
	 Tuberculosis screening provided for all exposed personnel (Guide, p 23) 					X
	 Training and implementation of procedures for bites, scratches, or injuries associated with macaques (Guide, p 23) 					X
	 PPE is provided including gloves, arm protection, face masks, face shields, or goggles (Guide, p 21) 					X
	 Injuries associated with macaques are carefully evaluated and treatment implemented (Guide, p 23) 					X
•	Occupational safety and health of field studies is reviewed by OSH committee or office $(Guide, p.32)$					X
11.	Personnel Security NEW	A *	М	S	C	NA
•	Preventive measures in place include pre-employment screening, and physical and IT security ($Guide$, p 23)	X				
12.	Investigating & Reporting Animal Welfare Concerns	A*	M	S	C	NA
•	Methods for investigating and reporting animal welfare concerns are established (Guide, p 23) [must]	X				

 Reported concerns and corrective actions are documented (<i>Guide</i>, p 24) 	X
 Mechanisms for reporting concerns are posted in facility and at applicable website with instructions (Guide, p 24) 	X
 Includes multiple contacts (Guide, p 24) 	X
 Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection (Guide, p 24) 	X

^{*} **A** = acceptable

M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

NOTES:

- 1. Significant Deficiency: There has been a marked degredation in animal care between June 2018 and May 2019. Animal care staff were not adequately qualified. The problems with animal care are being addressed by the animal care contract turning over. A new contract will be in place by May 25, 2019. This contract includes a new emphasis on adequate training and appropriate QA practices.
- 2. There is a new emergency procedure for use in the fish facility. The new procedure was put into use during an extended campus wide power outage, and worked well.
- 3. There is an OARM project to address the aging batteries responsible for the memory in the HVAC control units. These are being replaced campus wide, including in the animal facility.
- 4. The list of emergency contacts maintained by building Security and OARM was recently updated. The Government Shutdown of January 2019 and the campus wide extended power outage thoroughly tested then revised the contact list.
- 5. Section 4, Protocol Review: New electronic protocol review and animal ordering applications have been rolled out. The bugs are still being addressed, but overall the new applications are functional.
- 6. Section 4, Protocol Review: The single housing and emergency contact form has been updated.
- 7. Section 5: There is a new IO: Wayne Cascio, NHEERL Director
- 8. Section 6: IACUC members and staff attended the 2019 NCABR IACUC Conference. ARPO staff completed the UAB Zebrafish course. IACUC members also attended 1 webinar in this 6 month period.
- 9. Section 8: A new animal health specialist was brought on to the animal care contract. The person filling this position will not convey to the new contract.

10. Section 9: There is a new training protocol in place now, but in general training of new staff lagged due to the old protocol expiring during the prolonged Government Shutdown.

Veterinary Care

Date:

CI	inical Care and Management NEW	A*	М	S	C	N/
	Veterinary program offers high quality of care and ethical standards (<i>Guide</i> , <u>p 105</u>) [must]	X				
	Veterinarian provides guidance to all personnel to ensure appropriate husbandry, handling, treatment, anesthesia, analgesia, and euthanasia (<i>Guide</i> , <u>p 106</u>)	X				
	Veterinarian provides oversight to surgery and perioperative care (<i>Guide</i> , <u>p 106</u>)	X				
	Veterinary care program is appropriate for program requirements (Guide, pp 113-114)	X				
•	Veterinarian(s) is familiar with species and use of animals and has access to medical and experimental treatment records ($Guide$, p 114)	X				
•	Procedures to triage and prioritize incident reports are in place (<i>Guide</i> , <u>p 114</u>)	X				
•	Procedures are in place to address:					
	 Problems with experiments to determine course of treatment in consultation with investigator(Guide, p 114) 	X				
	 Recurrent or significant health problems with the IACUC and documentation of treatments and outcomes (Guide, p 114) 	X				
	 Veterinary review and oversight of medical and animal use records (Guide, p 115) 	X				
•	Procedures established for timely reporting of animal injury, illness, or disease (<i>Guide</i> , p 114) [must]	X				
•	Procedures established for veterinary assessment, treatment, or euthanasia ($Guide$, p 114) [must]	X				
•	Veterinarian is authorized to treat, relieve pain, and/or euthanize (<i>Guide</i> , <u>p 114</u>) [must]	X				
۸.	nimal Procurement and Transportation/Preventive Medicine	A*	M	S	C	N

	X	
Procedures for lawful animal procurement are in place (Guide, p 106) [must]	V	
Sufficient facilities and expertise are confirmed prior to procurement (<i>Guide</i> , <u>p 106</u>)	X	
 Procurement is linked to IACUC review and approval (Guide, p 106) 	X	
 Random source dogs and cats are inspected for identification (Guide, p 106) 		X
 Population status of wildlife species is considered prior to procurement (<i>Guide</i>, p 106) 		X
• Population status of wildlife species is considered prior to procurement (Guide, <u>p 100)</u>	X	
 Appropriate records are maintained on animal acquisition (Guide, p 106) 	^	
 Animal vendors are evaluated to meet program needs and quality (Guide, p 106) 	X	
 Breeding colonies are based on need and managed to minimize numbers (Guide, p 107) 	X	
 Procedures for compliance with animal transportation regulations, including international requirements, are in place (Guide, p 107) [must] 	X	
	X	
 Transportation is planned to ensure safety, security and minimize risk (Guide, p 107) 		
 Movement of animals is planned to minimize transit time and deliveries are planned to ensure receiving personnel are available (Guide, pp 107- 108) 	X	
 Appropriate loading and unloading facilities are available (Guide, p 109) 	X	
	X	
Environment at receiving site is appropriate (Guide, p 109)		
 Policies in place on separation by species, source, and health status (Guide, pp 109, 111-112) 	X	
	X	
 Procedures in place for quarantine to include zoonoses prevention (Guide, p 110) 		
 Quarantined animals from different shipments are handled separately or physically separated (Guide, p 110) 		X

	Procedures in place for stabilization/acclimation (Guide, pp 110-111)	X				
	Policies in place for isolation of sick animals (Guide, p 112)	X				
•	Program is in place for surveillance, diagnosis, treatment and control of disease to include daily observation ($Guide$, p 112)	X				
	Diagnostic resources are available for preventive health program (<i>Guide</i> , <u>p 112</u>)	X				
. Sı	ırgery	A*	M	S	C	N
	Surgical outcomes are assessed and corrective changes instituted (<i>Guide</i> , <u>p 115</u>)	X				
•	Researchers have appropriate training to ensure good technique (<i>Guide</i> , <u>p 115</u>) [must]	X				
•	Pre-surgical plans are developed and include veterinary input (e.g., location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping) (<i>Guide</i> , p 116)	X				
•	Aseptic surgery is conducted in dedicated facilities or spaces, unless exception justified and IACUC approved ($Guide$, p 116)	X				
•	Surgical procedures including laparoscopic procedures are categorized as major or minor (<i>Guide</i> , pp 117-118)	X				
•	For nonsurvival surgery, the site is clipped, gloves are worn and instruments and area are clean (<i>Guide</i> , p 118)	X				
	Aseptic technique is followed for survival surgical procedures (Guide, pp 118-119)	X				
•	Effective procedures for sterilizing instruments and monitoring expiration dates on sterile packs are in place (<i>Guide</i> , <u>p 119</u>)	X				
٠	Procedures for monitoring surgical anesthesia and analgesia are in place ($Guide$, p 119)	X				
٠	For aquatic species, skin surfaces are kept moist during surgical procedures (<i>Guide</i> , <u>p</u> 119))
/ 8	Post-operative monitoring and care are provided by trained personnel and documented (e.g., thermoregulation, physiologic function, analgesia, infection, removal of skin closures) (<i>Guide</i> , pp 119-120)	X				
D-	ain, Distress, Anesthesia and Analgesia	A*	M	S	C	N

1	 Program complies with federal regulations for human and veterinary drugs(Guide, 115) [must] Animal users as a whole are still moving to comply with DEA 	p			X	
	Drug Storage and Control NEW	A*	M	S	C	N
	 Procedures and training are in place to ensure death is confirmed (Guide, p 124) [must] 	X				
	 Training is provided on appropriate methods for each species and considers psychological stress to personnel (Guide, p 124) 	X				
	 Standardized methods are developed and approved by the veterinarian and IACU that avoid distress and consider animal age and species (Guide, pp 123-124) 					
	 Methods are consistent with AVMA Guidelines on Euthanasia unless approved by t IACUC (Guide, p 123) 	he X				
	Euthanasia	A*	М	S	С	N
	 Special precautions for the use of paralytics are in place to ensure anesthesia¹⁴ (Guide, p 123) 	X				
	 Guidelines for selection and use of analgesics and anesthetics are in place and regularly reviewed and updated (Guide, p 122) 	X				
7	 Procedures are in place to assure antinoception before surgery begins (Guide, p 1 must) 					
1	 Nonpharmacologic control of pain is considered as an element of postprocedural of (Guide, p 122) 	are X				,
	 Painful procedures are monitored to ensure appropriate analgesic management (Guide, p 122) 	X				
	 Selection of analgesics and anesthetics is based on professional veterinary judgme (Guide, p 121) 		Ш			
1	 Guidelines for assessment and categorization of pain, distress and animal wellbein are provided during training (Guide, p 121) 	7				

 $^{^{14}}$ 2.31(d)(iv)(C) - "Procedures that may cause more than momentary or slight pain or distress to the animals will...not include the use of paralytics without anesthesia."

 Drug records and storage procedures are reviewed during facility inspections (Guide, p 115) Some IACUC members checked, some didn't. Inconsistent application of inspection this time around. Will do better next time. 	X		
 Procedures and policies are in place to ensure analgesics and anesthetics are used within expiration date (Guide, p 122) [must] 	X		
 Anesthetics and analgesics are acquired, stored, and their use and disposal are recorded legally and safely (Guide, p 122) It is now institutional policy that it is the PI's responsibility to maintain their own licenses and registrations. 		X	

^{*} **A** = acceptable

M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

NOTES:

- **1.** Animal users as a whole are still moving to comply with DEA requirements put in place last year. A change is still taking place. Some registrations have taken a long time between initial submission and receipt.
- 2. Some IACUC members checked, some didn't. Inconsistent application of inspection this time around. Will do better next time.
- **3.** It is now institutional policy that it is the PI's responsibility to maintain their own licenses and registrations.

Summarize the heating, ventilation and air conditioning (HVAC) systems for each animal facility, *including all satellite facilities*. Include *all animal holding rooms* (including satellite holding rooms), surgical facilities, procedure rooms, and support spaces integral to animal facilities (e.g., cage wash, cage and feed storage areas, necropsy, treatment).

Location/Building/Facility: Research Triangle Park, NC

In the text box below, provide a general description of the mechanical systems used to provide temperature, humidity and air pressure control. Include details such as:

- the source(s) of air and air recirculation rates if other than 100% fresh air
- treatment of air (filters, absorbers, etc.)
- design features such as centralized chilled water, re-heat coils (steam or hot water), individual room vs. zonal temperature
 and relative humidity control, the use of variable air volume (VAV) systems and other key features of HVAC systems
 affecting performance
- features that minimize the potential for adverse consequences to animal well-being (such as re-heat coils that fail closed or that are equipped with high-temperature cut-off systems), and
- how room temperature, ventilation, and critical air pressures are monitored and maintained in the event of a system or component failure, including notifying appropriate personnel in the event of a significant failure that occurs outside of regular working hours and/or other management systems used to respond to alerts or failures.

The RTPP uses 100% HEPA filtered fresh air throughout the vivarium. Seven Air Handling Units (AHUs) serve all of Building A. Only 5 AHUs are required to meet the building load; however, all AHUs that are available (not down for maintenance) are in service for energy conservation purposes. Thus, there is adequate redundancy with respect to the AHUs. Each unit is furnished with 30% efficient pre-filters, 95% efficient final filters, energy (heat) recovery coils, clean steam humidifiers, pre-heat coils and chilled water coils. Each animal holding module is equipped with a 99.7% in-line filter assembly, a variable air volume (VAV) airflow control unit and a reheat coil. The building is cooled with chilled water generated at the campus Central Utility Plant and heated with hot water generated in the EPA main mechanical room. Additionally, process steam is generated in the EPA main mechanical room. Backup chilled water, hot water and steam systems are in standby mode, available 24/7 in the event of primary system failure.

The EPA RTP campus uses an automated Building Air Supply system which is monitored by an on-site contractor 24/7; the Animal Care Staff also have access to the BAS data on a dedicated computer in their office suite. Should a problem arise, the on-site facility contractor has personnel on call 24/7 including weekends and holidays to respond and repair the HVAC system.

In the Table below, provide room-specific information requested. For each room within this location, indicate use, including the species for animal housing rooms. Measurement of air exchange rates and verification of relative pressure within animal housing rooms (excluding rooms housing aquatic species only) and cage washing facilities must be completed within the 12 months preceding completion of this Program Description. Air exchange rates may be important to maintain air quality in other areas; however, measurements may be left at the discretion of the institution. Information may be provided in another format, providing all requested data is included. [Note: Please remove the examples provided in the Table below.]

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified /
			(settings	to be verified)			(values to be measured)	Measured
A-180	supplies prep	70 +/-2 °F	Υ	68/75 °F	Υ		23.7	May 2019
A-192	supplies storage	70 +/-2 °F	Y	68/75 °F	Υ	+	7.2	May 2019
A-194	bedding storage	70 +/-2 °F	Υ	68/75 °F	Υ	+	7.4	May 2019
A-195	clean storage	70 +/-2 °F	Y	68/75 °F	Υ	+	14	May 2019
A-196	suite common	70 +/-2 °F	Y	68/75 °F	Υ	1 + 1	24	March 2019
A-196 B	animal holding	70 +/-2 °F	Y	68/75 °F	Υ	7 7 1	15	March 2019
A-196 C	animal holding	70 +/-2 °F	Y	68/75 °F	Υ		16	March 2019
A-196 D	animal holding	70 +/-2 °F	Y	68/75 °F	Υ	7	17	March 2019
A-196 E	animal holding	70 +/-2 °F	Υ	68/75 °F	Y		15	March 2019
A-196 F	airlock	No set point	n/a	n/a	n/a	+	0	March 2019
A-196 G	animal holding	70 +/-2 °F	Υ	68/75 °F	Y		16	March 2019

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified /
			100000	s to be verified)			(values to be measured)	Measured
A-196 H	animal holding	70 +/-2 °F	Υ	68/75 °F	Υ		17	March 2019
A-197	clean cage wash	70 +/-2 °F	Υ	68/75 °F	Y	1 - 4	34.3	May 2019
A-197	soiled cage wash	70 +/-2 °F	Y	68/75 °F	Y		66.5	May 2019
A-198	QC Laboratory	70 +/-2 °F	Υ	68/75 °F	Y	7	15	May 2019
A-199 A	South airlock	No set point	n/a	n/a	n/a	+	No exhaust	May 2019
A-199 B	North airlock	No set point	n/a	n/a	n/a	+	No exhaust	May 2019
A-276	suite common	70 +/-2 °F	Y	68/75 °F	Υ		19.8	March 2019
A-276 A	animal holding	70 +/-2 °F	Υ	68/75 °F	Υ	+	13.6	March 2019
A-276 B	animal holding	70 +/-2 °F	Y	68/75 °F	Υ	+	13.1	March 2019
A-276 C	animal holding	70 +/-2 °F	Y	68/75 °F	Y	+	13.9	March 2019
A-276 D	animal holding	70 +/-2 °F	Y	68/75 °F	Y	+	16.5	March 2019
A-276 E	animal holding	70 +/-2 °F	Y	68/75 °F	Υ	+	14.1	March 2019
A-276 F	animal holding	70 +/-2 °F	Y	68/75 °F	Υ	+	12.7	March 2019
A-276 G	animal holding	70 +/-2 °F	Υ	68/75 °F	Υ	+	13.9	March 2019
A-277	suite common	70 +/-2 °F	Y	68/75 °F	Y	1 ·	26.1	March 2019
A-277 A	animal holding	70 +/-2 °F	Υ	68/75 °F	Υ	+	12.1	March 2019
A-277 B	animal holding	70 +/-2 °F	Υ	68/75 °F	Υ	+	11.8	March 2019

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified /
			1000	s to be verified)			(values to be measured)	Measured
A-277C	animal holding	70 +/-2 °F	Υ	68/75 °F	Y	+	12.8	March 2019
A-277 D	animal holding	70 +/-2 °F	Υ	68/75 °F	Y	+	16.2	March 2019
A-277 E	animal holding	70 +/-2 °F	Y	68/75 °F	Υ	+	12.8	March 2019
A-277 F	animal holding	70 +/-2 °F	Y	68/75 °F	Y	+	13.1	March 2019
A-277 G	animal holding	70 +/-2 °F	Y	68/75 °F	Y	+	14.6	March 2019
A-280	suite common	75 +/-2 °F	Y	73/78 °F	Y	7	14.3	March 2019
A-280 A	animal holding	75 +/-2 °F	Y	73/78 °F	Υ) = 3 2 0 0	23.3	March 2019
A-280 B	animal holding	75 +/-2 °F	Υ	73/78 °F	Υ	+	12.3	March 2019
A-280 C	animal holding	75 +/-2 °F	Υ	73/78 °F	Υ	+	10.9	March 2019
A-280 D	animal holding	75 +/-2 °F	Υ	73/78 °F	Y	+	11.1	March 2019
A-280 E	animal holding	75 +/-2 °F	Y	73/78 °F	Υ	+	13	March 2019
A-280 F	animal holding	75 +/-2 °F	Y	73/78 °F	Υ	+	13.9	March 2019
A-280 G	animal holding	75 +/-2 °F	Y	73/78 °F	Υ	+	12.8	March 2019
A-299 A	South airlock	No set point	n/a	n/a	n/a	+	No exhaust	March 2019
A-299 B	North airlock	No set point	n/a	n/a	n/a	+	No exhaust	March 2019
A-287	Men's Locker	70 +/-2 °F	Υ	68/75 °F	Υ	1 1	19.61	March 2019
A-289	Women's Locker	70 +/-2 °F	Υ	68/75 °F	Υ	10.41	17.45	March 2019

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified /
			1000	s to be verified)			(values to be measured)	Measured
A-376	suite common	70 +/-2 °F	Υ	68/75 °F	Υ	271	59.4	March 2019
A-376 A	animal holding	70 +/-2 °F	Υ	68/75 °F	Y	+	15	March 2019
A-376 B	animal holding	70 +/-2 °F	Y	68/75 °F	Υ	+	15.7	March 2019
A-376 C	animal holding	70 +/-2 °F	Υ	68/75 °F	Y	+	14.4	March 2019
A-376 D	animal holding	70 +/-2 °F	Y	68/75 °F	Y	+	12.2	March 2019
A-376 F	animal holding	70 +/-2 °F	Υ	68/75 °F	Y	+	15.3	March 2019
A-376 G	animal holding	70 +/-2 °F	Υ	68/75 °F	Υ	+	14.6	March 2019
A-376 H	animal holding	70 +/-2 °F	Υ	68/75 °F	Y	+	15.9	March 2019
A-377	suite common	70 +/-2 °F	Υ	68/75 °F	Υ	- 30	19.6	March 2019
A-377 A	animal holding	70 +/-2 °F	Y	68/75 °F	Y	+	15	March 2019
A-377 B	animal holding	70 +/-2 °F	Y	68/75 °F	Υ	+	15.2	March 2019
A-377 C	animal holding	70 +/-2 °F	Υ	68/75 °F	Υ	+	15	March 2019
A-377 D	animal holding	70 +/-2 °F	Υ	68/75 °F	Υ	+	17.3	March 2019
A-377 G	animal holding	70 +/-2 °F	Υ	68/75 °F	Υ	+	16.6	March 2019
A-377 H	animal holding	70 +/-2 °F	Υ	68/75 °F	Υ	+	15.9	March 2019
A-377 I	animal holding	70 +/-2 °F	Υ	68/75 °F	Υ	+	14.6	March 2019
A-380	suite corridor	72 +/-2 °F	Υ	68/75 °F	Υ	7	14.4	March 2019

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured March 2019 March 2019 March 2019 March 2019 March 2019
			1000	s to be verified)			(values to be measured)	
A-380 A	animal holding	72 +/-2 °F	Υ	68/75 °F	Y	+	14.1	March 2019
A-380 B	animal holding	72 +/-2 °F	Υ	68/75 °F	Y	+	14.6	March 2019
A-380 C	animal holding	72 +/-2 °F	Υ	68/75 °F	Y	+	13.9	March 2019
A-380 E	animal holding	72 +/-2 °F	Υ	68/75 °F	Y	+	14.2	March 2019
A-380 F	animal holding	72 +/-2 °F	Y	68/75 °F	Y	+	14.4	March 2019
A-380 G	animal holding	72 +/-2 °F	Υ	68/75 °F	Y	+	13.6	March 2019
A-386	suite corridor	72 +/-2 °F	Y	68/75 °F	Υ	3.1	10.1	March 2019
A-386 A	animal holding	72 +/-2 °F	Υ	68/75 °F	Y	+	18.9	March 2019
A-386 B	animal holding	72 +/-2 °F	Υ	68/75 °F	Y	+	18.3	March 2019
A-386 D	animal holding	72 +/-2 °F	Y	68/75 °F	Y	+	18.5	March 2019
A-386 E	animal holding	72 +/-2 °F	Y	68/75 °F	Υ	+	17.9	March 2019
A-386 F	animal holding	72 +/-2 °F	Υ	68/75 °F	Υ	+	17.3	March 2019
A-389	suite common	71 +/-2 °F	Υ	69/74 °F	Y	7	26.2	March 2019
A-389 A	animal holding	71 +/-2 °F	Υ	69/74 °F	Υ	+	16.2	March 2019
A-389 B	animal holding	71 +/-2 °F	Y	69/74 °F	Υ	+	15	March 2019
A-389 C	animal holding	71 +/-2 °F	Υ	69/74 °F	Υ	+	14.1	March 2019
A-389 E	animal holding	71 +/-2 °F	Υ	69/74 °F	Υ	+	13	March 2019

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified /
			1000	s to be verified)			(values to be measured)	Measured
A-389 F	animal holding	71 +/-2 °F	Υ	69/74 °F	Υ	+	15.4	March 2019
A-389 G	animal holding	71 +/-2 °F	Υ	69/74 °F	Y	+	14.4	March 2019
A-389 H	animal holding	71 +/-2 °F	Y	69/74 °F	Υ	+	14	March 2019
A-390	suite common	70 +/-2 °F	Υ	68/73 °F	Y	7	12.7	March 2019
A-390 B	procedure space	70 +/-2 °F	Y	68/73 °F	Y	neutral	41.5	May 2019
A-390 C	necropsy	70 +/-2 °F	Υ	68/73 °F	Y		25.8	May 2019
A-390 D	surgery post-op	70 +/-2 °F	Υ	68/73 °F	Υ	+	18	May 2019
A-390 E	surgery prep	70 +/-2 °F	Υ	68/73 °F	Υ	+	8.1	May 2019
A-390 F	surgery	70 +/-2 °F	Υ	68/73 °F	Υ	+	13.4	May 2019
A-390 G	vestibule	70 +/-2 °F	Υ	68/73 °F	Y	+	12.7	May 2019
A-399 A	South airlock	n/a	n/a	n/a	n/a	+	No exhaust	May 2019
A-399 B	North airlock	n/a	n/a	n/a	n/a	+	No exhaust	May 2019
A-476	suite common	71 +/-2 °F	Y	69/74 °F	Υ	7	57.4	March 2019
A-476 A	animal holding	71 +/-2 °F	Y	69/74 °F	Υ	+	15	March 2019
A-476 B	animal holding	71 +/-2 °F	Υ	69/74 °F	Υ	+	16.1	March 2019
A-476 C	animal holding	71 +/-2 °F	Υ	69/74 °F	Υ	+	14.8	March 2019
A-476 D	animal holding	71 +/-2 °F	Υ	69/74 °F	Υ	+	11	March 2019

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified /
			1000	s to be verified)			(values to be measured)	Measured
A-476 F	animal holding	71 +/-2 °F	Υ	69/74 °F	Υ	+	14.5	March 2019
A-476 G	animal holding	71 +/-2 °F	Υ	69/74 °F	Y	+	15.3	March 2019
A-476 H	animal holding	71 +/-2 °F	Y	69/74 °F	Υ	+	15	March 2019
A-477	suite common	70 +/-2 °F	Y	68/75 °F	Y	7	57.9	March 2019
A-477 A	animal holding	70 +/-2 °F	Y	68/75 °F	Y	+	14.7	March 2019
A-477 C	animal holding	70 +/-2 °F	Υ	68/75 °F	Y	+	14.4	March 2019
A-477 G	animal holding	70 +/-2 °F	Y	68/75 °F	Υ	+	14.9	March 2019
A-477 H	animal holding	70 +/-2 °F	Υ	68/75 °F	Y	+	16	March 2019
A-479	airlock	n/a	n/a	n/a	n/a	+	15.1	March 2019
A-479	cold room	n/a	n/a	n/a	n/a	NA	N/A	March 2019
A-479 A	decontamination	70 +/-2 °F	Υ	68/73 °F	Y		17.1	March 2019
A-479 C	animal holding	70 +/-2 °F	Υ	68/73 °F	Υ	+	10.9	March 2019
A-479 D	animal holding	70 +/-2 °F	Y	68/73 °F	Υ			March 2019
A-479 E	animal holding	70 +/-2 °F	Υ	68/73 °F	Υ	+	13.9	March 2019
A-479 F	animal holding	70 +/-2 °F	Υ	68/73 °F	Υ	+	10.4	March 2019
A-479 G	procedure room	70 +/-2 °F	Υ	68/73 °F	Υ	-	35.3	March 2019
A-479 H	suite foyer	n/a	n/a	n/a	n/a	7	12	March 2019

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified /
				s to be verified)			(values to be measured)	Measured
A-486	suite corridor	n/a	n/a	n/a	n/a	11.37.1	15.7	March 2019
A-486 A	animal holding rat	70 +/-2 °F	Υ	68/73 °F	Y	+	15.2	March 2019
A-486 B	animal holding rabbit	66 +/-2 °F	Y	64/69 °F	Υ	+	13.5	March 2019
A-486 D	animal holding rat	72 +/-2 °F	Y	70/75 °F	Y	+	11.1	March 2019
A-486 E	animal holding rat	71 +/-2 °F	Y	69/74 °F	Y	+	12.9	March 2019
A-486 F	animal holding/rabbit exercise	66 +/-2 °F	Υ	64/69 °F	Y	+	14.5	March 2019
A-489	suite common	n/a	n/a	n/a	n/a	3	26.5	March 2019
A-489 A	animal holding	70 +/-2 °F	Υ	68/73 °F	Υ	+	16.2	March 2019
A-489 B	animal holding	70 +/-2 °F	Y	68/73 °F	Y	+	15.2	March 2019
A-489 C	animal holding	70 +/-2 °F	Υ	68/73 °F	Y	+	15.3	March 2019
A-489 E	animal holding	70 +/-2 °F	Y	68/73 °F	Υ	+	13.7	March 2019
A-489 F	animal holding	70 +/-2 °F	Y	68/73 °F	Υ	+	16.5	March 2019
A-489 G	animal holding	70 +/-2 °F	Y	68/73 °F	Υ	+	16	March 2019
A-489 H	animal holding	70 +/-2 °F	Υ	68/73 °F	Υ	+	16.7	March 2019
A-490	suite common	70 +/-2 °F	Υ	68/73 °F	Υ	-	16.6	March 2019
A-490 B	procedure space	70 +/-2 °F	Υ	68/73 °F	Υ	neutral	42.2	May 2019
A-490 C	necropsy	70 +/-2 °F	Υ	68/73 °F	Υ	7	25.8	May 2019

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured		
	0.70		(settings to be verified)							
A-490 D	surgery post-op	70 +/-2 °F	Υ	68/73 °F	Υ	221	7.8	May 2019		
A-490 E	surgery prep	70 +/-2 °F	Υ	68/73 °F	Y	+	7.8	May 2019		
A-490 F	surgery	70 +/-2 °F	Y	68/73 °F	Υ	+	12.9	May 2019		
A-490 G	vestibule	70 +/-2 °F	Y	68/73 °F	Y	+	14.5	May 2019		
A-499 A	South airlock	n/a	n/a	n/a	n/a	+	No exhaust	May 2019		
A-499 B	North airlock	n/a	n/a	n/a	n/a	+	No exhaust	May 2019		
A- 576/577	airlock	n/a	n/a	n/a	n/a	+	11.1	March 2019		
A-576	suite common	71 +/-2 °F	Y	69/74 °F	Υ	1 4	19.3	March 2019		
A-576 A	animal holding	71 +/-2 °F	Y	69/74 °F	Y	+	17	March 2019		
A-576 B	animal holding	71 +/-2 °F	Υ	69/74 °F	Y	+	17.4	March 2019		
A-576 C	animal holding	71 +/-2 °F	Y	69/74 °F	Y	+	17	March 2019		
A-576 D	animal holding	71 +/-2 °F	Υ	69/74 °F	Υ	+	12.9	March 2019		
A-576 F	animal holding	71 +/-2 °F	Y	69/74 °F	Υ	+	17.1	March 2019		
A-577	suite common	71 +/-2 °F	Y	69/74 °F	Υ	3	17.4	March 2019		
A-577 A	animal holding	71 +/-2 °F	Υ	69/74 °F	Υ	+	16.3	March 2019		
A-577 C	animal holding	71 +/-2 °F	Υ	69/74 °F	Υ	+	12	March 2019		
A-577 D	animal holding	71 +/-2 °F	Υ	69/74 °F	Υ	+	16.4	March 2019		

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified /
			(values to be measured)	Measured				
A-577 E	animal holding	71 +/-2 °F	Υ	69/74 °F	Y	+	16.1	March 2019
A-577 F	animal holding	71 +/-2 °F	Υ	69/74 °F	Y	+	17.1	March 2019
A- 578/579	airlock	n/a	n/a	n/a	n/a	+	16.3	March 2019
A-578	suite common	71 +/-2 °F	Y	69/74 °F	Y	1 - y - f	18	March 2019
A-578 A	animal holding	71 +/-2 °F	Y	69/74 °F	Y	+	17	March 2019
A-578 B	animal holding	71 +/-2 °F	Υ	69/74 °F	Y	+	17.6	March 2019
A-578 C	animal holding	71 +/-2 °F	Υ	69/74 °F	Υ	+	17.7	March 2019
A-578 D	animal holding	71 +/-2 °F	Υ	69/74 °F	Υ	+	16.8	March 2019
A-578 F	animal holding	71 +/-2 °F	Y	69/74 °F	Y	+	15.8	March 2019
A-579	suite common	72 +/-2 °F	Υ	70/75 °F	Y	14	19.7	March 2019
A-579 A	animal holding	72 +/-2 °F	Y	70/75 °F	Υ	+	15.8	March 2019
A-579 C	animal holding	72 +/-2 °F	Υ	70/75 °F	Υ	+	13	March 2019
A-579 D	animal holding	72 +/-2 °F	Y	70/75 °F	Y	+	114.7	March 2019
A-579 E	animal holding	72 +/-2 °F	Υ	70/75 °F	Υ	+	14.4	March 2019
A-579 F	animal holding	72 +/-2 °F	Y	70/75 °F	Y	+	14.9	March 2019
A- 585/586	front airlock	n/a	n/a	n/a	n/a	+	14.8	March 2019
A- 585/586	rear airlock	n/a	n/a	n/a	n/a	+	22	March 2019

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured		
			(settings to be verified)							
A-585	suite common	n/a	n/a	n/a	n/a	11.35	18.1	March 2019		
A-585 A	animal holding	70 +/-2 °F	Υ	68/73 °F	Y	1-5	17.2	March 2019		
A-585 B	animal holding	70 +/-2 °F	Y	68/73 °F	Υ		17	March 2019		
A-585 C	animal holding	70 +/-2 °F	Υ	68/73 °F	Y	1	16.7	March 2019		
A-585 D	animal holding	70 +/-2 °F	Y	68/73 °F	Y	1000	16.3	March 2019		
A-586	suite common	n/a	n/a	n/a	n/a		25.9	March 2019		
A-586 B	animal holding	70 +/-2 °F	Υ	68/73 °F	Υ		18.3	March 2019		
A-586 C	animal holding	70 +/-2 °F	Υ	68/73 °F	Υ	(A)	17.1	March 2019		
A-586 D	animal holding	70 +/-2 °F	Υ	68/73 °F	Υ	100	19.3	March 2019		
A-586 E	animal holding	70 +/-2 °F	Y	68/73 °F	Y	-	15.8	March 2019		
A-584	procedural	69 +/-2 °F	Y	67/72 °F	Υ	+	44	May 2019		
A-580	decontamination	72 +/-2 °F	Υ	70/75 °F	Υ	+	33	May 2019		
A-580 A	airlock	n/a	n/a	n/a	n/a	+	21	May 2019		
A-587	necropsy	70 +/-2 °F	Υ	68/73 °F	Υ		20	May 2019		
A-599 A	South airlock	n/a	n/a	n/a	n/a	+	No exhaust	March 2019		
A-599 B	North airlock	n/a	n/a	n/a	n/a	+	No exhaust	March 2019		
H-106 D	animal holding	73 +/-2 °F	Υ	70/76 °F	Υ	+	15	March 2019		

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified /
			(settings	to be verified)			(values to be measured)	Measured
H- 104	animal holding	73 +/-2 °F	Υ	70/76 °F	Y	+	14	March 2019

[Create additional rows by pressing TAB in the bottom-right box.]

Copy and repeat the Description and Table for each location, including all satellite housing locations.

Appendix 12: Aquatic Systems Summary – Part I

Please summarize water management and monitoring information programs for each animal facility, including all satellite facilities, rooms, enclosures. The following key will assist you in completing the form:

- (1) List location of aquaria, including outdoor enclosures (ponds or outdoor tanks). If indoors, list building and room number. Note that all species housed at the same location and maintained via the same design and monitoring may be listed in the same row.
- (2) Please indicate if embryonic (E), larval (L), juvenile (J) or Adult (A)
- (3) Group tanks (ponds, outdoor tanks, multiple aquaria) are arranged as arrays with shared water supply; individual aquaria have exclusive water handling systems.
- (4) Indicate water type, e.g., fresh, brackish, or marine.
- (5) Indicate water pre-treatment, e.g., dechlorination, rough filters.
- (6) Indicate water circulation, e.g., static, re-circulated, constant flow, or some combination of these. If applicable, indicate water exchange frequency and amount (percentage).
- (7) Provide a key word for filtration employed, e.g., biological, chemical, mechanical, and type (e.g., mechanical-bead filter). A diagram may be provided showing the flow of water, filtration, source of "make-up" water and amount replaced daily.

Part I

Appendix 12: Aquatic Systems Summary – Part I

	Species			Sys	stem Design		
Location (1)	(2)	Group / Individual (3)		Pre-treatment (5)	Circulation (6)	Filtration (7)	Disinfection (e.g., UV, ozone)
A280-D,	Zebrafish- L, J, A	Group	Fresh	RO water w/ salt and sodium bicarbonate	Recirculated	Mechanical- polyester fiber pads and fine mesh filter bags Biological- fluidized bed Biological- moving bed ceramic media bioreactor Chemical – activated carbon in a mesh filter bag	UV
A280 - E, F, G	Zebrafish- L, J, A	Group	Fresh	RO water w/ salt and sodium bicarbonate	Recirculated	Mechanical- polyester fiber pad Biological- fluidized bed Chemical – activated carbon canister	UV

Appendix 12: Aquatic Systems Summary - Part I

Species			Sy	stem Design		
(2)	Group / Individual (3)	THE RESERVE AND ADDRESS OF THE PARTY OF THE	Pre-treatment (5)	Circulation (6)	Filtration (7)	Disinfection (e.g., UV, ozone)
Zebrafish- E, L	Group/ individual	Fresh	0-4 days 10% Hank's solution 5days – 2 wks Deionized distilled water w/salt added	Static 750 ml glass bowls w/ tops, 6, 12, 24, 48 or 96 well plates with lids.	None water is changed twice daily/ 25 to 100% of the water is changed once daily.	none
Zebrafish E, L	Group/ individual	Fresh	0-4 days 10% Hank's solution 5days – 2 wks Deionized distilled water w/salt added	Static 750 ml glass bowls w/ tops, 6, 12, 24, 48 or 96 well plates with lids.	None water is changed twice daily/ 25 to 100% of the water is changed once daily.	none
	Zebrafish-E, L	Zebrafish-E, L Group/ Zebrafish Group/ Zebrafish Group/	Zebrafish- E, L Group/ Individual (3) Group/ Group/ individual Fresh Zebrafish Group/ Fresh	Group / Individual (3) Water Type (4) Pre-treatment (5) Zebrafish-E, L Group/ individual Fresh Group/ individual	Circulation (6) Circulatio	Zebrafish E, L Group/ individual Group/ individual Fresh Group/ individual Group/ individual Fresh Group/ individual Group/ individual Group/ individual Fresh Group/ individual Group/ individu

Note: Records of equipment maintenance (filter changes, UV bulb changes, probe changes, calibrations, etc.) should be available for review.

[Create additional rows by pressing TAB in the bottom-right box.]

Appendix 12: Aquatic Systems Summary – Part II

The following key will assist you in completing this form:

- (1) In these columns, please indicate monitoring frequency, e.g. daily, weekly, monthly or other point sampling frequency; continuous/real time, or none, if applicable. Also indicate method of control (heaters versus room HVAC, hand versus auto dosing, etc.).
- (2) Indicate other parameters and their monitoring frequency, e.g., alkalinity, total hardness, conductivity, chlorine/chloramine.

Part II

Indicate in	the boxes belo	w the frequ	iency	of mo		nitoring ng and		ntrol for the	following parameters. (1)
Location (from Part I)	Temperature	Salinity	рН	NH ₄	NO ₂	NO ₃	Dissolved O ₂	Total Dissolved Gases	Other. Please List (2):
A280-D, E, F, G	C-heater	C-AD	C- AD	W- PS-H		W-PS- H	W-PS-H	None	total hardness –M-PS-H chlorine-each time rack is taken down, disinfected, and set back up
B252-A Zebrafish larvae	C-incubator	None	W- PS- H	None	W-PS- H	W-PS- H	None	None	
E564 Zebrafish larvae	C-incubator	None	W- PS- H	None	W-PS- H	W-PS- H	None	None	

Note: This information may be provided in another format, provided that all requested data is included.

[Create additional rows by pressing TAB in the bottom-right box.]

Appendix 13: Primary Enclosures and Animal Space Provisions

Please complete the Table below considering performance criteria and guiding documents (e.g., Guide, Ag Guide, ETS 123 and/or other applicable standards) used by the IACUC/OB to establish adequacy of space provided for all research animals including traditional laboratory species, agricultural animals, aquatic species, and wildlife when reviewing biomedical, field, and agricultural research studies.

Species	Dimensions of Enclosure (cage, pen, tank*, corral, paddock, etc.)	Maximum Number Animals / Enclosure	Guiding Document Used to determine the Institution's Space Standards (Guide, Ag Guide, ETS 123, Other)	Enclosure Composition & Description**
Mice	19" x 10 ½"x 6"	10 adults	The Guide	polycarbonate, open top under rack filter paper
Mice	14 ½" x 6" x 5 ¼"	4 adults	The Guide	polycarbonate,
Mice	12 ½" x 9 ¼" x 6"	5 adults	The Guide	polycarbonate, open top under rack filter paper
Mice	8 ¾" x 14" x 5"	5 adults	The Guide	polycarbonate, open top under rack filter paper
Mice	14 ½" x 7 ¾" x 7 ½"	2 adults	The Guide	polycarbonate, IVC
Rats	19" x 10 ½"x 8"	2 adults	The Guide	polycarbonate/polysulfone, open top under rack filter paper
Rats	16 3/4" x 10 ½" x 7 ½" 14" x 14" x 7"	2 adults up to 500 gms 2 adults	The Guide	polycarbonate, IVC

Appendix 13: Primary Enclosures and Animal Space Provisions

Species	Dimensions of Enclosure (cage, pen, tank*, corral, paddock, etc.)	Maximum Number Animals / Enclosure	Guiding Document Used to determine the Institution's Space Standards (Guide, Ag Guide, ETS 123, Other)	Enclosure Composition & Description**
Rats	14 1/4 " x 7 ³ / ₄ " x 7 1/2" 14" x 12" x 7 ¹ / ₂ "	1 adult 2 adults greater	The Guide	polycarbonate, IVC
Rabbits	19 ½" x 28" x 18" 30" x 31" x 18"	1 adult	The Guide	stainless steel w/polycarbonate inserts
Zebrafish	9 liters 6 liters	5 adults/liter	The Guide	polycarbonate

^{*}For aquatic species, provide tank volume.

**Include descriptors such as open-topped, static microisolator, individually-ventilated cage systems (IVCS).

Please describe the cleaning and disinfection methods in the Table below. Note the washing/sanitizing frequency and method for each of the following:

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
		Micro-environme	nt	
Solid-bottom cages (static)	mechanical washer	1-2x weekly	Pentasodium triphosphate, sodium carbonate, disodium metasilicate tetrasodium EDTA	
Solid-bottom cages (IVC)	mechanical washer	weekly and Every Other Week (E/O/W)	Pentasodium triphosphate, sodium carbonate, disodium metasilicate tetrasodium EDTA	Singly housed animals in Tecniplast IVC caging are sanitized E/O/W.
Suspended wire-bottom or slotted floor cages	mechanical washer	Weekly	Pentasodium triphosphate, sodium carbonate, disodium metasilicate tetrasodium EDTA	
Cage lids	mechanical washer	E/O/W	Pentasodium triphosphate, sodium carbonate, disodium metasilicate tetrasodium EDTA	
Filter tops	mechanical washer	E/O/W	Pentasodium triphosphate, sodium carbonate, disodium metasilicate tetrasodium EDTA	
Cage racks and shelves	mechanical washer	E/O/W	Pentasodium triphosphate, sodium carbonate, disodium metasilicate tetrasodium EDTA	

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Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Cage pans under suspended cages	mechanical washer	weekly	Pentasodium triphosphate, sodium carbonate, disodium metasilicate tetrasodium EDTA	
Play pens, floor pens, stalls, etc.	mechanical washer	monthly	Pentasodium triphosphate, sodium carbonate, disodium metasilicate tetrasodium EDTA	
Corrals for primates or outdoor paddocks for livestock	n/a	n/a		
Aquatic, amphibian, and reptile tanks and enclosures	Hand washing and mechanical washer	at spawning	Mechanical (no detergent compound)	
Feeders	mechanical washer	E/O/W	Pentasodium triphosphate, sodium carbonate, disodium metasilicate tetrasodium EDTA	
Watering devices	mechanical washer	Weekly and E/O/W	Pentasodium triphosphate, sodium carbonate, disodium metasilicate tetrasodium EDTA	
Exercise devices and manipulanda used in environmental enrichment programs, etc.	mechanical washer	weekly	Pentasodium triphosphate, sodium carbonate, disodium metasilicate tetrasodium EDTA	
Transport cages	mechanical washer	After each use	Pentasodium triphosphate, sodium carbonate,	

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
			disodium metasilicate tetrasodium EDTA	
Operant conditioning & recording chambers, mechanical restraint devices (chairs, slings, etc.)				
Euthanasia chambers	mechanical washer	After each use	Pentasodium triphosphate, sodium carbonate, disodium metasilicate tetrasodium EDTA	
Macro-Environment				
Animal Housing Rooms:				
Floors	hand washing	daily	Potassium peroxomonsulfate, Sodium dodecylbenzene sulphonate, sulfamic acid	
Walls	hand washing	monthly	Potassium peroxomonsulfate, Sodium dodecylbenzene sulphonate, sulfamic acid	
Ceilings	hand washing	as needed	Potassium peroxomonsulfate, Sodium dodecylbenzene sulphonate, sulfamic acid	

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Ducts/Pipes	hand washing	as needed	Potassium peroxomonsulfate, Sodium dodecylbenzene sulphonate, sulfamic acid	
Fixtures hand washing		as needed	Potassium peroxomonsulfate, Sodium dodecylbenzene sulphonate, sulfamic acid	
Corridors:				
Floors hand washing		daily	Potassium peroxomonsulfate, Sodium dodecylbenzene sulphonate, sulfamic acid	
Walls hand washing		as needed	Potassium peroxomonsulfate, Sodium dodecylbenzene sulphonate, sulfamic acid	
Ceilings hand washing		as needed	Potassium peroxomonsulfate, Sodium dodecylbenzene sulphonate, sulfamic acid	
Ducts/Pipes hand washing		as needed	Potassium peroxomonsulfate, Sodium dodecylbenzene sulphonate, sulfamic acid	
Fixtures hand washing		as needed	Potassium peroxomonsulfate, Sodium dodecylbenzene sulphonate, sulfamic acid	

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Support Areas (e.g.,	surgery, procedure rooms, etc.); complet	te for each area:		
Floors	hand washing	daily	Potassium peroxomonsulfate, Sodium dodecylbenzene sulphonate, sulfamic acid	
Walls hand washing as needed Potassium peroxomonsulfate, So dodecylbenzene		peroxomonsulfate, Sodium		
Ceilings	lings hand washing as needed Potassium peroxomonsulfate, Sodium dodecylbenzene sulphonate, sulfamic acid		peroxomonsulfate, Sodium dodecylbenzene	
Ducts/Pipes	dodecylbenzene		peroxomonsulfate, Sodium	
Fixtures hand washing as needed		Potassium peroxomonsulfate, Sodium dodecylbenzene sulphonate, sulfamic acid		
Implements (note wh	ether or not shared):			
Mops	pps mechanical washer		Potassium peroxomonsulfate, Sodium dodecylbenzene sulphonate, sulfamic acid	
Mop buckets	Poptagodium triphograpato		£	

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)	
			disodium metasilicate tetrasodium EDTA		
Aquaria nets	chemical	continuous	Benzalkonium chloride and methylene blue	Nets remain in Net Soak (maquat) when not in use; weekly they are rinsed with clean water, dipped in chlorine dip tank, rinsed again with clean water, and left to air dry before being returned to Net Soak solution.	
Other					
Other:					
Vehicle(s)	interior-hand washing exterior-mechanical	interior-after each animal transport exterior- as needed	Potassium peroxomonsulfate, Sodium dodecylbenzene sulphonate, sulfamic acid		
Other transport equipment (list) mechanical		daily (after use)	Potassium peroxomonsulfate, Sodium dodecylbenzene sulphonate, sulfamic acid Benzyl-C12 ammonium chlorides, quatenary ammonium compounds	wheels are sprayed with disinfectant (Virkon) and outer areas are wiped down with disinfectant (Sani Wipes) if moved between suites	

^{*}Please provide chemical, not trade name.

Clout ingredients (Pentasodium triphosphate, sodium carbonate, disodium metasilicate tetrasodium EDTA),

Virkon ingredients (Potassium peroxomonsulfate, Sodium dodecylbenzene sulphonate, sulfamic acid)

Sani-cloth wipes ingredients (Benzyl-C12 ammonium chlorides, quatenary ammonium compounds)

Jungle Net Soak ingredients (Benzalkonium chloride and methylene blue)

Bleach (diluted 1700 mL bleach & 30 gallons water)

Appendix 15: Facilities and Equipment for Sanitizing Materials

In the Tables below, summarize the facilities and equipment used to sanitize animal related equipment (tunnel washer, bottle washer, rack washer, bulk autoclave, hand-washing area, bedding dispensing unit, etc.). Note that some descriptions may be combined if all share identical features (e.g., all rack washers).

[Note: Please remove the examples provided in the Table below.]

Building Room No.		Equipment Type	Safety Feature(s)	Methods of Monitoring Effectiveness		
A	197	2 Rack washers	Emergency "off" button; labeled exit door, de-energizing cord on both sides, instructional signage	Guarantee 180-degree hot water rinse; temperature-sensitive tape used weekly; RODAC plates of caging tested quarterly		
Α	197	2 Tunnel washers	Emergency "off" button; instructional signage	Guarantee 180-degree hot water rinse; temperature-sensitive tape used weekly; RODAC plates of caging tested quarterly		
Α	197	Bulk autoclave	Emergency "off" button	ATP-based luminescence swabs performed weekly Test ampules weekly		
Α	197	Bottle filler	Emergency "off" button	N/A		
A	197	Bedding dispensing unit	Emergency "off" button	N/A		
A	197	DI water rinse unit for aquaria	Limited to PPE	Visual assessment		
Α	580	Autoclave	Emergency "off" button	ATP-based luminescence swabs performed weekly Test ampules weekly		
Α	490	Autoclave	Emergency "off" button	ATP-based luminescence swabs performed weekly Test ampules weekly		
Α	390	Autoclave	Emergency "off" button	ATP-based luminescence swabs performed weekly Test ampules weekly		

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Appendix 16: Lighting Summary

Using the Table below, summarize the lighting system(s) for the animal housing facility(ies). For each species or holding room type, list light intensity (range), construction features (e.g., water resistance), photoperiod (light:dark) and control (e.g., automatic versus manual, phasing). For systems automatically controlling photoperiod, describe override mechanisms (including alarms, if applicable).

For what it is worth: All information here will be moot by the end of December 2019. All fluorescent lights across the entire EPA campus, including lights in the vivarium, will be replaced with new LED lights by the end of the calendar year. What those light levels will be is currently unknown.

Location: A Building Vivarium

Room Type ^(a)	Light Intensity Range	Lighting Fixture Construction Features ^(b)	Photo- period (hrs)(c)	Photoperiod and Lighting Control	Override Mechanisms (if applicable)	
Rodent Holding Rooms	Avg 30 ft- candles	Recessed, water resistant	12:12	Automatic via wall- mounted timer box	Mechanical on/off switch	
Fish Holding Rooms (A280 suite)	Avg 30 ft- candles	Recessed, water resistant	14:10 Automatic via wall-mounted timer box		Mechanical on/off switch	
Surgery	Not measured	Recessed, water resistant; plus arm-mounted surgical lamps	NA N/A		N/A	
Necropsy	Not measured	Recessed, water resistant; plus arm-mounted surgical resistant lamps	NA	N/A	N/A	
Cage-Washing Room	Not measured	Recessed, water resistant	NA N/A		N/A	
A486 E	20-30 ft- candles	Recessed, water resistant	14:10 Reversed light cycle, 14 dark:10 light, Automatic via wall- mounted timer box		Mechanical on/off switch	
A479 F	Avg 30 ft- candles	Recessed, water resistant	14:10	Automatic via wall- mounted timer box	Mechanical on/off switch	
A477 A	Avg 30 ft- candles	Recessed, water resistant	14:10 Automatic via wall- mounted timer box Mech		Mechanical on/off switch	

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Appendix 16: Lighting Summary

Room Type ^(a)	Light Intensity Range	Lighting Fixture Construction Features ^(b)	Photo- period (hrs)(c)	Photoperiod and Lighting Control	Override Mechanisms (if applicable)	
		lightbulb in incubator with a timer	12:12	Incubator with a timer	Manual switch	
B 254 Not lightbulb measured timer		lightbulb in incubator with a timer	12:12	Incubator with a timer	Manual switch	
E 564	Not measured	lightbulb in incubator with a timer	12:12	Incubator with a timer	Manual switch	
H 104A	Not measured	Fluorescent hanging fixture.	12:12	Manual switch	Manual switch	

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Repeat Location and Table as necessary for each location, including satellite housing locations.

⁽a) A list of each room is not needed; group or cluster rooms by species or function

⁽b) Include such features as water resistance, red lighting, etc.

⁽c) Note if light cycle inverted/reversed.

Appendix 17: Satellite Housing Facilities

Note: In the Program Description Section 2. IV. (Physical Plant), item C., describe the criteria used to determine a "Satellite Animal Holding Area." In the Table below, summarize these animal housing areas. Note that the total square footage for all each of these must also be included in the Summary of Animal Housing and Support Sites (Appendix 2), and applicable information regarding these areas included in the Heating, Ventilation, and Air Conditioning (HVAC) Summary (Appendix 11) and Lighting Systems Summary (Appendix 16).

Building	Room(s)	Person Responsible	Species Used	Approximate Area (ft ² or m ²) Devoted to Housing	Maximum Period of Stay	Purpose / Rationale / Justification	Construction Features and Finishes
В	251	PI	Zebrafish	242 ft²	14 days	Exposure of embryos and fry	Incubator in lab
В	254	PI	Zebrafish	253 ft²	14 days	Exposure of embryos and fry	Incubator in lab
E	564	PI	Zebrafish	121 ft²	14 days	Exposure of embryos and fry	Incubator in lab
н	104A	PI	Rat, mouse	110 ft ²	Has not been used in 2 years	Diesel exposures	Cinderblock and concrete construction, paint and epoxy finishes

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